Chinese Pharmaceutical and Biological Products Registration Test

Disposable Pulsed Lavage System
Clinical test report

Applicant: Guangzhou Clean Medical Products Manufacturing Co., Ltd.

Product name: Disposable pulsed lavage system

Trialing medical institution: Guangzhou People's First Hospital

Data management and statistical analysis:
Guangzhou People's First Hospital, and
Institute for Chemical Carcinogenesis, Guangzhou Medical College

Clinical Trial Leader: Zhang Guangming

Statistical Leader: Bin Xiao agricultural

Summary Prepared by: Zhang Guangming, Wang Wei

Test start and end dates: April- November 2009

Clinical Trial Summary Time: December 2009

Data repository: Guangzhou First People's Hospital of clinical drug experiment base

Contact: Wu Lin, Ni Suiqin

Phone 020 -81048106

Researchers Signature Page

Researchers statement:

I have read the "disposable pulse lavage system Clinical trials research report", I promise I have provided the experimental data that is both true and reliable, and my level of knowledge within the scope of this report confirms accuracy of the description of the experimental procedure and results.

Clinical Trials Unit responsible: Guangzhou First People's Hospital

Clinical Trial Leader: Zhang Guangming, Professor, Chief Physician

Phone: 020-81048246

Signature:

Table of Contents

Abbreviations Table 3

Ethics 4

Abstract ……..... 5

Foreword 9

Research purposes ……..... 10

Subjects and Methods …… . . . .…….. 10

Results of clinical trials ……..... 20

Discussion and conclusion ……..... 29

Abbreviations GLOSSARY

Chinese name	English name (abbreviations)
不良事件	Adverse Event
严重不良事件	Serious Adverse Event
意向性分析	Intention analysis
全分析	Full-Analysis
符合方案数据集	Protocol Compliance Dataset
统计分析系统 SAS 6.12	Statistical Analysis System SAS 6.12
社会科学统计软件包 S PSS 15.0	Statistical Package for Social Sciences S PSS 15.0
方差分析 ANOVA	ANOVA analysis of variance
平均数	Mean
标准差	Standard deviation
试验组	Test group
对照组	Contral group
肝功能 ALT, AST	Liver function ALT, AST
肾功能	Renal BUN, Cr
卡方分层分析	Chi-square analyzes stratified
卡方检验	Chi-square test
精确概率法检验	Fisher test
秩和检验	Wilcoxon test
符号秩和检验	Signed Rank test

Ethics

Guangzhou First People's Hospital Ethics Committee in 2009 March on disposable pulse lavage system for the clinical trial protocol, informed consent and case report forms for discussion. Guangzhou First People's Hospital Ethics Committee by the 7 members, of which 6 members attended the meeting, attended by members after careful review, that the clinical trials conducted in accordance with << Declaration of Helsinki >> ethical principles, unanimously adopted the clinical studies program, and signed consent for clinical trials.

After the experiment, after verification that all eligible subjects were signed informed consent, agree to participate in clinical trials included only after clinical trials.

Abstract

1. Study name: Disposable pulse lavage system for clinical trials

2. Product registration inspection: by Guangdong Provincial Medical Device Quality Supervision and Inspection Station, the product of the indicators are in line with provincial standards, test report No. ZC083061.

3. Researchers: Clinical trials in charge: Zhang Guangming Guangzhou First People's Hospital Chief Physician

4. Test start and end dates:

First subject enrollment time: April 2009; End subjects enrolled completion: November 2009.

5. Purpose:

The clinical trial is to evaluate the Guangzhou Clean Medical Products Manufacturing Co., Ltd. production of "disposable pulse lavage system" clinical usage safety and efficacy.

6. Experimental design:

A randomized clinical trial approach which meets the conditions of the patients were randomly divided into experimental and control groups, respectively, using the "disposable pulsed lavage" and traditional debridement method to evaluate "disposable pulse lavage's" clinical efficacy and safety.

7. Efficacy indicators:

The primary efficacy endpoint: After two weeks the wound inflammatory response was evaluated

Secondary outcome measures: incidence of adverse reactions, bacterial cultures and colony counts and so on.

8. Test case into the group:

50 patients were enrolled, of which Guangzhou First People's Hospital divides into Experimental group of 25 patients and the control group of 25 cases, including removing 0 cases, shedding 0 cases.

9. Use:

All damage in accordance with the general requirements of debridement were first brush to wash the wound with soap and affected limb circumference corresponding normal skin; wash the wound according to whether the test product is divided into experimental group and control group were 0.9% saline rinse solution; rinse amount of liquid: wound size ≤ surface area of 1% to 1000 ml;> 1%, ≤ 5%, to 2000 ml;> 5%, ≤ 10%, to 3000 ml;> 10%, ≤ 20%, to 4000 ml

Test group of patients on which "Disposable pulse lavage" is used. Control group of patients in accordance with the requirements of traditional debridement of the wound with normal saline flush directly.

10. Clinical evaluation criteria:

(A) Efficacy observations:

1, two weeks after the wound inflammatory response was evaluated: the inflammatory response red, swollen, hot, exudates based on four indicators for the evaluation of each project and the total score plus inflammation as a final evaluation score, the higher the score more severe inflammatory response. Rating criteria are as follows:

Item Level	None	Light	Medium	Heavy
Red	0 0	1 1	2 2	3 3
Swollen	0 0	1 1	2 2	3 3
Hot	0 0	1 1	2 2	3 3

Exudates	0 0	1 1	2 2	3 3

2, Incidence of adverse reactions: Number of cases of adverse reactions/Total number of cases in the group

3, bacterial cultures and colony counts: in the wound secretions taken before and after washing bacterial culture. Take before and after washing the wound secretions in 0.5ml doing things colony counting. Statistical respectively before and after washing the wound with bacterial culture and colony counting without statistically significant difference between the two methods without statistical difference.

(B). Safety Observation Project:

Including: temperature, pulse, blood, urine; liver function (ALT, AST), renal function (BUN, Cr).

11. Statistical analysis methods:

Measurement of data: two groups before and after treatment or between group analysis, the first on the variable distribution normality test. Obey the normal distribution, with a group t test or paired t test, ANOVA missing persons, with t 'test; non-normal distribution, with the Wilcoxon rank sum test or signed rank (Signed Rank) testing and other non-parametric statistical methods or row data conversion. Taking into account processing, sequencing, individual, center or other factors, using analysis of variance; when considering the impact of covariates using analysis of covariance. Count data: the two groups before and after treatment or between group analysis, using Fisher test and the Wilcoxon rank sum test; dichotomous data and level data comparison, taking into centers or other factors, the effect of using the correction center Test.

12. Efficacy Results

1 The primary efficacy analysis:

Clinical trials (flushing) after the test group and the control group compared the degree of change of clinical symptoms, red, swollen, hot to change clinical symptoms showed no significant difference ($p > 0.05$); clinical trial may be considered (flushing)

after the test group and the control group clinical symptoms consistent with the degree of change; experimental group exudate level change compared with control group, the difference was statistically significant ($p = 0.012 < 0.05$) that the clinical trials (flush) the degree of abnormality exudate after the test group than the control group. After 14 days the average wound area point: experimental group and the control group 0.0 ± 0.0 0.0 ± 0.0 ($p > 0.005$) identical; wound healing can be considered as the test group at a predetermined test time and the control group agreed. Repeated measures analysis of variance of clinical trials before and after the counting of bacterial culture results were statistically analyzed, before the test, test, test 6 weeks after counting of bacterial culture results before discharge test group ($p = 0.003 < 0.05$) and the control group ($p = 0.015 < 0.05$) were statistically significant, that counts before the test results were higher than bacterial culture test and prior to discharge; Results of the test group bacteria counts in all trials with the control group, the difference was not statistically significant ($p > 0.05$), can be considered experimental and control groups bacterial count results are consistent.

13. Safety analysis:

Finished selecting observation phase and test phase was observed in all cases, were not aware of any security issues. This test is considered experimental observation phase used washer, research methods, observation period in this experiment subjects were seen security problems (experimental group and control group completed the experimental observation, the incidence of adverse events are 0% (after the test group and the control group compared by statistical analysis showed no significant difference, $p = 1.00$), can be considered: Use Guangzhou Clean Medical Products Manufacturing Co., Ltd. production of disposable pulse lavage (test unit 25 patients) and use of conventional washing method (control group of 25 cases) of the same security.

14. Clinical trials concluded:

50 patients aged 18-59 years (35.6.9 ± 11.2 years), 39 males and 11 females; 50 test subjects, the test group of 25 patients used Guangzhou Clean Medical Products Manufacturing Corp's Disposable Pulse Lavage; control group 25 cases, used conventional washing methods; object of study in both groups observed on project results, the statistical tests and analysis, in addition to heart rate, pulse number of trial group were slightly lower than the control group (in normal physiological range), the other two groups, the difference was not statistically significant ($p > 0.05$); that the use Guangzhou Clean Medical Products Manufacturing Co., Ltd. production of disposable pulse lavage the safety and use of conventional washing method consistent with the results. Results of the test group bacteria counts in all trials with the control group, the difference was not statistically significant ($p > 0.05$), can be considered experimental and control groups bacterial count results are consistent. Clinical trials after two weeks the wound inflammatory response evaluation score, the test group and the control group, the difference was not significant ($p = 0.064 > 0.05$). Test group exudate level change compared with control group, the difference was statistically significant ($p = 0.012 < 0.05$) that the clinical trials (flush) the degree of abnormality exudate after the test group than the control group. That the use of pulse lavage, postoperative wound exudate less than the conventional washing method, with high efficiency, safety, reduce wound exudate and promote healing.

Foreword

Cleaning open wounds, surgical clinical generally taken directly washing fluid or partial resection of the polluting clean way, this may result in cleaner ways: ① Rinse the waste can not be recovered, causing contamination extended; ② heavily polluted site in the process of brushing cause secondary damage; ③ wash the wound caused by incomplete wound infection, resulting in delayed healing or even nonunion. Disposable pulse lavage can attract ejected pulsed high pressure water, the use of high pressure, pulse jet of water / mist flush pollution sites, compared with the traditional method of high degree of automation, simple operation; using pulses can be retained in the sediment deep wound rinse and wash fast, patient pain, saving fluid, reduce labor intensity; and in the process of flushing the timely recovery of flushing waste, to achieve safe and efficient cleaning results.

The purpose of this clinical validation is Guangzhou Clean Medical Products Manufacturing Co., Ltd. production of "disposable pulse lavage" on the clinical safety and efficacy evaluation. Guangzhou Clean Medical Products Manufacturing Co., Ltd. production of "disposable pulse lavage" by the Guangdong Provincial Medical Device Quality Supervision and Inspection Station, the product of the indicators are in line with provincial standards, the test report number ZC083061. Verify compliance with the Declaration of Helsinki, in line with medical ethics, and by the First People's Hospital of Guangzhou clinical trials ethics committee for consideration and approval. Has been registered by China's medical equipment required to complete the preliminary studies of the product and by the State Food and Drug Administration China Pharmaceutical and Biological Products for product safety, effectiveness checks, according to national medical device product registration requirements, now proceed to clinical validation of the product, in a multi-center, large sample to observe the efficacy and safety of the product.

Test product does not affect patients' living environment such as temperature, humidity, atmospheric composition and pressure; does not produce chemical

substances, waste and fluids discharge; without concomitant consumables or accessories; no maintenance or calibration.

Research purposes

Under normal conditions of use in accordance with the provisions of the product clinical trials for evaluation of disposable pulse lavage in clinical use has the expected safety and efficacy.

Subjects and Methods

1. Clinical GENERAL INFORMATION (disease, total number of cases and case selection):

The test is conducted Guangzhou First People's Hospital of experimental observation of selected cases of 50 people. All meet the inclusion criteria diagnostic test after entering randomized. Were randomly grouped, divided into: test group of 25 patients in the control group of 25 patients. Experimental group of 25 patients to take "Disposable pulse lavage" approach control group of 25 patients, according to the traditional debridement of the wound requires saline flush test directly. No dropout cases.

1. Clinical trial methodology (including the necessary control group settings):

Will be selected for the clinical trial were randomly divided into test group, control groups, the test group of 25 patients used to take "Disposable pulse lavage" method, the control group, 25 patients in the traditional requirements for physiological debridement saline wash the wound directly test for comparative assessment of efficacy. Adopt a "Disposable pulse lavage" on the way for wound repair flush whether better clinical efficacy and safety. 1:1 inductees were randomly assigned to experimental and control groups. Random number table generated by the PEMS3.1 statistical software to run.

1． Inclusion criteria:

A) the principle of voluntary patients enrolled, and signed the "informed consent."

B) There are fresh wounds or trauma wound infection (within 72 hours after burn).

C) selected patient trauma patients, aged 18-65 years old, male or female.

D）I signed the informed consent of patients. There autonomy, voluntary subjects. Obtaining informed consent process should be consistent with clinical solutions and GCP requirements.

2． Exclusion criteria:

（1）Does not meet the inclusion criteria of the subjects;

（2）Are known to have severe allergies;

（3）Long-term use of corticosteroids;

（4）Poor general condition, for example, obviously hypoalbuminemia (serum albumin <25g / L), glucose not control (postprandial blood glucose> 11mmol / L) diabetes, uric acid has not been controlled gout;

（5）Special injury factors associated with the injury, such as radiation injury, toxic injury, snake bites or rabies;

（6）Combined cardiovascular, liver, kidney and hematopoietic system severe primary disease, mental illness;

（7）Combined with active bleeding or shock or visceral injury;

（8）Liver and kidney function was abnormal;

（9）Pregnancy or prepare pregnant women, lactating women;

（10）Suffering from other drug treatment effects are observed disease testing products;

（11）Subjects were reluctant to participate in the trial with or without treatment;

（12）I can not express informed patient consent.

3． Clinical trial subjects exit conditions and standards (shedding of cases):

（1）All met the inclusion criteria, informed consent, and has conducted randomized trials using products, but did not complete the observation period specified program

subjects (although not complete the observation period if the subjects, and the wound has healed you Not as shedding cases).

（2）Subjects were unwilling to continue to conduct clinical trials, made out of clinical trials.

（3）Withdrew from the study subjects were not explicitly raised, but not timely referral, subjects with poor compliance, can not adhere to treatment.

（4）The patients of serious adverse events or serious adverse reactions.

（5）Patients in the clinical trials process of serious complications, complications, should not continue to be tested.

（6）Subjects deteriorated, must take urgent measures to deal with those.

（7）For cases falling in the case report form shall (CRF) recorded on the Causes, as far as possible by telephone, letters, etc. Ask grounds, and try to complete the most recent data recording CRF tables on subjects corresponding clinical evaluation. If for adverse events and loss, followed by the final judgment and test products for stakeholders, must be recorded in the CRF and notify the implementer.

4．Excluding Case Standard:

（1）the subjects do not meet the inclusion criteria subjects, including the inclusion criteria, exclusion criteria;

（2）in combination with the experimental indications promote healing of drugs or other treatments are;

（3）has been randomly assigned, the subjects did not receive treatment.

5 ．Product distribution and use:

5.1 Test product packaging:

According to the trial were randomly assigned tables, uniform numbers on the test chemicals, packaging, packaging indicate the product number, product name, indications, contraindications, validity, manufacturers and "for clinical validation" and so forth.

Test Group: Product topical plastics sealed packaging, pack containing a W-201 disposable pulse lavage, production batch number: L20081201; Guangzhou Clean Medical Products Manufacturing Co., Ltd. produces and provides.

Control group: saline.

5.2 Test Product Distribution:

Will follow good coding test product dispensed, distributed together to participate in clinical trials unit, random number test product test product 25 parts.

Each study should have a special management unit test products, the subjects included, in accordance with experimental guinea pigs were randomly distributed or reference table which test product registration "experimental issuing registration form", return the remaining product concentration implementation unit or press relevant provisions of the destruction.

5.3 Test goods inventory:

Researchers in the subjects initial use, referral should pay attention to registration, inventory number of products used by each participant to determine its compliance with the product, decide whether to continue to participate in the trial subjects and recover the remaining product .

6 . Guinea pigs save:

Test samples by the testing center to save someone unified management.

7 . Combination therapy:

To exclude the role of other drugs affect all subjects during clinical trials may not be used on skin wound healing others promote healing effect of the drug or a similar product efficacy testing proprietary and external use and so on.

If subjects enrolled subjects who met eligibility criteria, and combined with other diseases continue to be in a clinical trial medication, or whose condition requires treatment do need additional drugs or treatment, should be carried out in a detailed case report form Record the name of the drug (or treatment), the dosage, the number of drugs, medication time.

8. Age, gender, source of cases, vital signs, physical examination of cases, causes wound, the wound area, wounds, blood pressure, pulse, respiration, blood, urine, liver function, kidney function.

9． Trial period Observations:

Experimental observation of the treatment of postoperative inflammation wounds two weeks, the incidence of adverse reactions, taken before and after washing the wound secretions in the bacterial culture and colony count.

10 . Security Analysis:

Finished selecting observation phase and testing phase of the cases observed, in addition to withdraw cases and unchecked cases, but twice before and after treatment were carried out laboratory tests. Physical examination, blood pressure, pulse, respiration, blood, urine, liver function, kidney function, and other aspects to compare. For each phase of testing may produce allergic reactions, adverse events, as well as experimental observation of clinical safety evaluation level for analysis.

11 ： Evaluation:

1, two weeks after the wound inflammatory response was evaluated: the inflammatory response red, swollen, hot, exudate based on four indicators for the evaluation of each project and the total score plus inflammation as a final evaluation score, the higher the score more severe inflammatory response.

2, the incidence of adverse reactions:

3, bacterial cultures and colony counts: in the wound secretions taken before and after washing bacterial culture. Take before and after washing the wound secretions in 0.5ml doing things colony counting. Statistical respectively before and after washing the wound with bacterial culture and colony counting without statistically significant difference between the two methods without statistical difference.

Three statistical methods used and evaluation methods:

1．The evaluation criteria:

Experimental group compared with the control group wound healing were compared using two t-test was used to compare the total efficiency x^2 test. $P < 0.01$ for the difference was very significant; $P < 0.05$ for the difference between the two groups was significant; $P > 0.05$ for the difference was not statistically significant.

Two groups of patients in age, gender and disease severity was no significant difference.

According to this test purpose, generally do not need follow-up, but clinical trials have found that indicators of abnormal safety testing must be carried out follow-up and should be recorded in detail.

2．Safety evaluation:

One: safe, without any adverse reaction; safety indicators examination no abnormalities.

Two: relatively safe, with mild adverse reactions, do not need any treatment can continue to use; safety indicators examination no abnormalities.

Three: There are security issues, there is moderate adverse reactions or safety indicators are slightly abnormal, so treatment can continue to use.

Four: serious adverse reactions due to discontinuation; checks or security indexes obvious abnormalities.

3． Adverse events, adverse reaction recording and reporting methods:

For adverse events occurred during the test, it should be kind, extent, occurrence time, duration, treatment measures, such as treatment and outcome after recorded in CRF, and the comprehensive consideration of comorbidities, concomitant medications, based on the evaluation of its test the relevance of irradiated pigskin by physicians recorded in detail. Due to adverse events, adverse reactions and discontinue use of the medical device cases should be follow-up investigation, detailed records of the results.

Security detection index (blood, urine, liver function, kidney function) if the treatment, after treatment, abnormal, must be at the appropriate time for review, and truthfully records and subjects the disease, treatment, etc. for comprehensive analysis, the test to determine whether the irradiated pigskin.

Adverse events and study drug (or medical device) to determine the relationship criteria: Identify adverse events and study drug (or medical device) whether there is a

causal relationship, according to the Ministry of Health Adverse Drug Reaction Monitoring Centre has developed a standard (GAO Dong Chen and other "adverse drug reactions surveillance Guide, "Chinese Pharmaceutical Technology Press, 1996). Judgment of five: causality judgment of affirmation, probably, possibly, doubtful and impossible.

Adverse events and study drug (or medical device) to determine the relationship criteria:

Identify adverse events and study drug (or medical device) whether there is a causal relationship, according to the Ministry of Health Adverse Drug Reaction Monitoring Centre has developed a standard (GAO Dong Chen and other "Adverse Drug Reaction Monitoring Guide," Chinese Medical Science and Technology Press, 1996). Judgment of five: causality judgment of affirmation, probably, possibly, doubtful and impossible.

Serious adverse events are recorded and reported: clinical trials of any serious adverse events, the investigators shall immediately adopt appropriate measures to protect the subjects, and immediately report the research units and responsible units, ethics committees, implementers, and in the State within 24 hours of Administration. Meanwhile researchers must fill in serious adverse event table to record the time of occurrence of serious adverse events, severity, duration, and outcome measures. Statistical analysis by the staff undertake statistical analysis tasks, and participate from the experimental design, implementation to analyze and summarize the entire process. Pilot programs and case report forms completed the development of statistical analysis plan.

4. Statistical Methods

4.1 statistical analysis software SPSS15.0 SAS6.12 or

4.2 Inspection Standard: Uniform sided test with $\alpha = 0.05$, $p \leq 0.05$ were considered statistically significant.

4.3 Quantitative data: given the sample size, mean, standard deviation, minimum, median, maximum, 95% CI description of statistical indicators. Or between the two

groups before and after treatment comparison group, the first on the variable distribution normality test. Obey the normal distribution, with a group t test or paired t test, ANOVA missing persons, with t 'test; non-normal distribution, with the Wilcoxon rank sum test or signed rank (Signed Rank) testing and other non-parametric statistical methods or row data conversion. Taking into account processing, sequencing, individual, center or other factors, using analysis of variance; when considering the impact of covariates using analysis of covariance.

4.4 Qualitative (level) data: the frequency of various types and the composition ratio of descriptive statistical analysis indicators. Or between the two groups before and after treatment comparison group, with the Fisher exact test and the Wilcoxon rank sum test; dichotomous data and level data comparison, taking into centers or other factors, the effect of using the correction center test.

5．Specific statistical program

5.1 Analysis of patients enrolled and completion, entering each of the centers listed in the overall number of cases, and lists the excluded list of cases fall.

5.2 Baseline data comparability analysis: FAS analysis. Measurement data for age, weight, vital signs related to pre-treatment, pre-treatment condition calculus, physical and chemical testing before treatment, etc., using the t test or Wilcoxon rank sum test; For qualitative (level) data severity, grading, drug allergies, past medical history, etc., using Fisher's exact test.

5.3 Evaluation: FAS, PPS analysis.

5.3.1 Analysis of variance: Inclusion processing order, individual, centers and other factors, analyze the impact of these factors on efficacy.

5.3.2 Comprehensive efficacy analysis: The two groups before treatment, during and after comparing the situation. Another use of the centers Test was to evaluate the clinical efficacy.

5.3.3 self efficacy analysis:

5 .3.4 parallel efficacy analysis:

5 .3.5 Classification symptom efficacy analysis:

5 .4 Analysis of patient compliance:

5 .5 Treatment safety assessment:

Four: Clinical evaluation of criteria:

1. Safety Observation Project

Including: temperature, pulse, blood, urine;

Liver function (ALT, AST), renal function (BUN, Cr).

2. Curative Effects Observation Project:

1, two weeks after the wound inflammatory response was evaluated: the inflammatory response red, swollen, hot, exudate based on four indicators for the evaluation of each project and the total score plus inflammation as a final evaluation score, the higher the score more severe inflammatory response. Rating criteria are as follows:

Item Level	No	Light	In	Weight
Red	0 0	1 1	2 2	3 3
Swollen	0 0	1 1	2 2	3 3
Hot	0 0	1 1	2 2	3 3
Exudate	0 0	1 1	2 2	3 3

2, the incidence of adverse reactions:

Number of cases of adverse reactions

Total number of cases in the group

3, bacterial cultures and colony counts: in the wound secretions taken before and after washing bacterial culture. Take before and after washing the wound secretions in 0.5ml doing things colony counting. Statistical respectively before and after washing the wound with bacterial culture and colony counting without statistically significant difference between the two methods without statistical difference.

Five clinical trials recordkeeping requirements

1 All patients were observed according clinical trial program, fill out case report form.

2 Two medical records and case report forms as original records can not be changed, do not change any corrections original records, but to use additional narrative justification by physicians participating in clinical trials signed and dated.

3 clinical trial data should be recorded in a variety of laboratory, outpatient cases should stick to the original report on the case report form.

4 in the normal range of laboratory data should be recorded on the high or clinically significant data outside the acceptable range must be verified by a physician to participate in clinical trials to make the necessary instructions.

5 should be in treatment, the treatment time points after each observation recorded once observed symptoms, signs, etc. (if not each observation time point were observed to be in close proximity to the time point ± 2 days at the end of the test or observation).

6 blood, urine, liver function, kidney function before the test, each end of treatment tested once (see above specific number of cases detected).

Six data retention

Researchers should agree to keep all research data, including confirmation of all subjects (can effectively check the records of different materials, such as CRF and hospitals original records), all of the original have signed informed consent, CRF, detailed records of pharmaceutical distribution (use of the device or medical records), etc. Clinical trial data should be kept to the test five years after termination.

All raw data, documentation, test reports, summary reports and clinical trials should be as a result of preservation, archives should be stored in an orderly manner, you can quickly and easily get all retrieve raw data, laboratory reports, test plans and interim reports and summary report. Shall designate a person responsible for the management of archives. Without approval, shall not enter the file room. Stored in archives or reference should be made of the information indexed for easy retrieval.

All data in this experiment are the property of the perpetrators, in addition to the State Food and Drug Administration requirements, without the written consent of implementers, researchers in any form to third parties.

Seven quality control

Overall responsibility by the principal investigator, the investigator specific implementation and enforcement. Include the following:

1 . The hospital laboratories participating in clinical trials to establish a unified assay targets, standard operating procedures and quality control procedures;

2 . Special inspection by the person responsible for the project must be detected;

3 . Experimental system to periodically verify and calibrate equipment;

4 . Participate in clinical trials, researchers must have clinical trials expertise, qualifications and abilities, after qualification, personnel requirements are relatively fixed;

5 . Before the start of clinical trials training: pre-service training through clinical trials enable researchers to clinical trial program and its specific targets, meaning the full understanding and awareness. All clinical trials and laboratory personnel in strict accordance with SOP program operations;

6 . Data recording to timely, direct, accurate, clear, signed and dated;

7 . Regular self-examination of data records to the accuracy, completeness, correct an error in accordance with the method specified.

Eight quality assurance

1 Implementers and researchers should fulfill their respective responsibilities, and strictly follow the clinical trial program, the use of standard operating procedures to ensure that the clinical trial quality control and quality assurance system implementation. Clinical trials and discoveries about all observations should be verified at each stage of data processing must be carried out quality control to ensure data integrity, accurate, truthful and reliable;

2 ． Establishment of a multi-center trial Coordination Committee, the lead unit of a multi-center trial principal investigator overall responsibility for the Coordination Committee, the Senate inquiry research units and the implementer is responsible for coordinating committee. Coordination Committee is responsible for the implementation of the whole test, study and solve problems related tests. Perpetrators responsible and the State Food and Drug Administration to keep in touch.

3 ．Inspectors appointed by the implementers to ensure that the interests of clinical trial subjects are protected, recording and reporting of test data is accurate, complete and correct, to ensure compliance with the approved protocol testing, "Good Clinical Practice" and related regulations .

4 ． Drug supervision and management departments, implementers can entrust inspectors of clinical trials related activities and documents systematically examined to evaluate whether the test in accordance with the test plan, standard operating procedures and relevant regulatory requirements, the test data is timely, true, accurate and complete recorded.

5 ． Medical institutions participating in clinical trials and laboratory information and documents (including medical history) should be treated with the drug regulatory department inspections.

Results of clinical trials

A. Statistical results

1． Trial enrollment and completion:

The test is conducted Guangzhou First People's Hospital of experimental observation, using the standard methods included a total of 50 test subjects elected, all in compliance with test diagnostic inclusion criteria, using a group of independent design, test before and after the self-control methods, experimental observation, Guangzhou Clean Medical Products Manufacturing Co., disposable pulse lavage (test units) washing, and conventional flushing (control group), the elections into the 50 test subjects observed in clinical trials, no dropouts cases.

Clinical trials (flushing) before the clinical observation status indicators, the test group and the control group, the difference was not statistically significant ($p > 0.05$); clinical trial may be considered (flushing) before the test and control groups in clinical trials indicators consistent with observations .

Clinical trials (flushing) before the test group and the control group, the clinical significance of observed indicators of clinical judgment

Clinical trials (flushing) before the clinical significance of the clinical outcome measures discrimination, the test group and the control group, WBC indicators clinical significance difference was statistically significant ($p = 0.041 < 0.05$); clinical trial may be considered (flushing) Former WBC clinical abnormalities observed indicators Number of test group than the control group.

Clinical trials (flushing) before the clinical significance of the remaining indicators of clinical observation, the test group and the control group, the difference was not statistically significant ($p > 0.05$).

4 Clinical Trials (flushing) before the second week after the test, prior to discharge experimental group and control group, the clinical results of analysis of observed indicators

Table 12 clinical trials (flushing) before the test two weeks later, before discharge test group and the control group, the clinical results of analysis of observed indicators

Clinical trials (flushing) before the test two weeks later, before discharge test group and the control group, the clinical results observed indicators using repeated measures analysis of variance: the experimental group WBC ($p = 0.001$), PLT ($p = 0.030$) was observed indicators of results, before rinsing flushing two weeks later, before discharge itself statistically significant difference ($p <0.05$), the remaining outcome measures were not statistically different; control group WBC ($p = 0.035$), body temperature ($p = 0.000$) was observed indicator results, rinse Before flushing two weeks later, before discharge itself statistically significant difference ($p <0.05$);

Before rinsing, rinse two weeks later, before discharge test group and the control group, the difference was statistically significant ($p <0.05$), the other outcome measures were not statistically different, think before rinsing, rinse two weeks after discharge preclinical OUTCOME MEASURES result, the test and control groups in clinical trials Indicator results are basically consistent.

Table 13 Clinical trials (flushing) after experimental group and the control group, the clinical significance of observed indicators of clinical judgment

Clinical trials (flushing) Clinical significance of clinical judgment OUTCOME MEASURES: WBC clinical significance of discrimination, the test group and the control group, the difference was statistically significant ($p = 0.041 <0.05$), that determine the clinical significance of abnormal WBC levels lower than the experimental group the control group; remaining clinical significance of observed indicators, the test group and the control group, the difference was not statistically significant ($p> 0.05$); may be considered experimental and control groups in clinical trials Indicator results are basically consistent.

Table 14 clinical trials (flushing) after experimental group and the control group, the clinical symptoms of the degree of change

Clinical trials (flushing) after the test group and the control group compared the degree of change of clinical symptoms, red, swollen, hot to change clinical symptoms showed no significant difference ($p> 0.05$); clinical trial may be considered (flushing) after the test group and the control group clinical symptoms consistent with the degree

of change; experimental group exudate level change compared with control group, the difference was statistically significant (p = 0.012 <0.05) that the clinical trials (flush) the degree of abnormality exudate after the test group than the control group.

a) Use effect (FAS), safety evaluation (SAS)

Table 1 5 clinical trials before and after the indicator results of bacterial culture

(p=0.015 Using repeated measures analysis of variance of clinical trials before and after the counting of bacterial culture results were statistically analyzed, before the test, test, test 6 weeks after counting of bacterial culture results before discharge test group (p = 0.003 <0.05) and the control group (p = 0.015 <0.05) were statistically significant, that counts before the test results were higher than bacterial culture test and prior to discharge;

Results of the test group bacteria counts in all trials with the control group, the difference was not statistically significant (p> 0.05), can be considered experimental and control groups bacterial count results are consistent.

Table 16 clinical trials evaluate the inflammatory response after two weeks the wound (Score)

Clinical trials after two weeks the wound inflammatory response evaluation score, the test group and the control group, the difference was not significant (p = 0.064> 0.05), that the use of disposable irrigator, surgical wound inflammation score after two weeks the experimental group the same score with the control group.

Table 17 clinical trials before and after allergies, adverse events, withdrawals Analysis

Of clinical trials before and after allergies, adverse events, exit test conditions and the effective cases and other cases analyzed by chi-square test, the test group and the control group was not statistically significant (p> 0.05), that clinical trials before and after allergy history, adverse events, exit test conditions and the effective cases, etc. as the experimental group and the control group.

Second, the main statistical conclusions

1 General Information

(1) subjects enrolled situations: Table 1-3 (PPAS)

50 cases of trial subjects are in line with the inclusion criteria, by group, paired design itself into one flush tests. 50 cases were completed subjects selected observation phase, no dropouts. All 50 cases observed subjects entered the testing phase, the subjects of experimental group of 25 patients in the control group of 25 patients completed the entire experimental observation phase.

(2) Before the test, the test group and the control group comparability analysis:

Into groups, matching the design itself, suggesting that with good comparability balance. Experimental observation stage of the analysis methods, test group and control groups were matched their repeated measures analysis of variance. Experimental and control groups in age, gender, test conditions and test agency, location, etc. By comparison, the difference was not statistically significant ($p > 0.05$), comparable with good tips, balance.

Experimental observation stage of the analysis method uses its own matching design, measurement data using repeated measures analysis of variance or paired t test, count data using the chi-square test or direct probabilities test.

2. Effectiveness: Table 4-9 (FAS)

All test subjects 50 cases, 50 cases of complete observation phase selection, efficiency of 100%; subjects entered the testing phase was observed 50 patients completed the study subjects 50 cases observation phase, efficiency of 100%, in line with the number of valid test requirements requirements.

Compliance Analysis: All test subjects 50 cases, respectively, using the Guangzhou Clean Medical Products Manufacturing Co., Ltd. production of disposable pulse lavage (test group of 25 patients), using conventional washing methods (control group, 25 cases). Into the experimental observation, actively cooperate with the test and completed a total of 50 cases observed all tests, so this test compliance rate was 50/50 = 100%.

3 Security Analysis: see Table 15-17 (FAS)

Finished selecting observation phase and Experimental observation phase of all cases, were not aware of any security issues. This test is considered experimental observation phase used washer, research methods, observation period in this

experiment subjects were seen security problems (experimental group and control group completed the experimental observation, the incidence of adverse events are 0% (after the test group and the control group compared by statistical analysis showed no significant difference, p = 1.00), can be considered: Use Guangzhou Clean Medical Products Manufacturing Co., Ltd. production of disposable pulse lavage (test unit 25 patients) and use of conventional washing method (control group of 25 cases) of the same security.

4. Experimental observations Rating: See Table 10-17 (FAS)

subjects aged 18-59 years (35.6.9 ± 11.2 years), 39 males and 11 females; 50 test subjects, the test group of 25 patients, the use of medical supplies, Guangzhou Clean Medical Products Manufacturing Co's disposable pulses lavage; control group 25 cases, the use of conventional washing methods; object of study in both groups observed on project results, the statistical tests and analysis, in addition to heart rate, pulse number of trial group were slightly lower than the control group (in normal physiological range), the other two groups, the difference was not statistically significant (p> 0.05); that the use Guangzhou Clean Medical Products Manufacturing Co., Ltd. production of disposable pulse lavage effect and safety and using conventional washing method consistent with the results.

Results of the test group bacteria counts in all trials with the control group, the difference was not statistically significant (p> 0.05), can be considered experimental and control groups bacterial count results are consistent.

Clinical trials after two weeks the wound inflammatory response evaluation score, the test group and the control group, the difference was not significant (p = 0.064> 0.05), that the use of disposable irrigator, surgical wound inflammation score after two weeks the experimental group the same score with the control group.

5. Clinical trials found that adverse events and side effects of treatment situations:

This study found no adverse events and side effects.

6 . Clinical trials, the conclusion:

Guangzhou Clean Medical Products Manufacturing Co., Ltd. production of "disposable pulse lavage" in the clinical validation phase, as a wound wash equipment, is easy to use, safe and efficient.

The above analysis can be considered, in this experiment the materials used (disposable pulse lavage) on wound rinse is safe. Use of disposable pulse lavage, reduces postoperative wound exudate less than the conventional washing method, with high efficiency, safety, reduce wound exudate and promote healing.

7. Indications, scope, contraindications and precautions:

Indications: For the treatment of all open wounds to prevent wound infection.

Contraindications and precautions: no contraindications.