**RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES BANGALURU, KARNATAKA**



COMPLETED PROFORMA FOR REGISTRATION OF SUBJECT

FOR DISSERTATION IN M.S.(AYURVEDA)

**TITLE**

**“A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF *KASEESADI AVACHOORNANA* AND *ARAGWADHA* *AVACHOORNANA* IN MANAGEMENT OF DUSTA VRANA W.S.R TO NON-HEALING ULCER”**

**BY**

**DR. AISHWARYA BELLARY**

IST YEAR P.G SCHOLAR,

DEPT. OF P.G STUDIES IN SHALYA TANTRA

**GUIDE**

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PROFESSOR

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**NAME OF THE INSTITUTE**

**SDM TRUST’S**

**AYURVEDIC MEDICAL COLLEGE,**

**DANIGOND POST GRADUATION CENTRE,**

**PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE,**

**DR. SIDDHANT NAGAR, TERDAL – 587315**

**2021-2022**

**FROM,**

**DR. AISHWARYA BELLARY**

1ST YEAR P.G. SCHOLAR,

DEPARTMENT OF SHALYA TANTRA

SDM Trust’s Ayurvedic Medical College

Danigond Post-graduation Centre,

Padma Ayurvedic Hospital & research centre, Terdal.

**TO,**

**THE REGISTRAR**

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES,

BANGALURU, KARNATAKA.

**THROUGH,**

**THE PRINCIPAL**

SDM Trust’s Ayurvedic Medical College,

Danigond Post-Graduation Centre,

Padma Ayurvedic Hospital and Research Centre, Terdal.

**Subject: Submission of Completed Proforma for Registration of the Synopsis of Dissertation work in M.S(Ayu).**

Respected Sir/Madam,

I request you to kindly register the below mentioned subject in my name for the submission of the dissertation to the Rajiv Gandhi University of health sciences, Bengaluru for partial fulfilment M.S (Ayurveda) in *SHALYA TANTRA*.

**TITLE:**

**A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF *KASEESADI AVACHOORNANA* AND *ARAGWADHA AVACHOORNANA* IN MANAGEMENT OF DUSTA VRANA W.S.R TO NON-HEALING ULCER**

Here with, I am enclosing the completed Proforma for the registration of the subject for dissertation in M.S (Ayurveda) in *SHALYA TANTRA.*

Thanking you sir,

Place: Terdal Yours’s faithfully

Date: (Dr. AISHWARYA BELLARY)

**RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES BANGALURU, KARNATAKA**

**ANNEXURE - II**

**PERFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION**

|  |  |  |
| --- | --- | --- |
| **1.NAME OF THE CANDIDATE AND ADDRESS** | : | DR. AISHWARYA BELLARY  1ST YEAR PG SCHOLAR  SDM TRUST’S AYURVEDIC MEDICAL COLLEGE,  DANIGOND POST-GRADUATION CENTER, PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE, TERDAL 587315, KARNATAKA |
| **PERMANENT ADDRESS** | : | DR. AISHWARYA BELLARY  D/O SUBRAMANNYA BELLARY  A/P: HAGARIBOMMANAHALLI  DT: VIJAYANAGARA  STATE: KARNATAKA |
| **2. NAME OF THE INSTITUTION** | : | SDM TRUST’S AYURVEDIC MEDICAL COLLEGE,  DANIGOND POST-GRADUATION CENTER, PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE, TERDAL 587315, KARNATAKA |
| **3. COURSE OF STUDY AND SUBJECT** | : | M.S(AYURVEDA), SHALYA TANTRA |
| **4. DATE OF THE ADMISSION OF COURSE** | : | 8 APRIL 2023 |
| **5. NAME OF THE TOPIC** | : |  |
| **A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF KASEESADI AVACHOORNANA AND ARAGWADHA AVACHOORNANA IN MANAGEMENT OF DUSTA VRANA W.S.R TO NON-HEALING ULCER.** | | |

**6. BRIEF RESUME OF INTENDED WORK**

**6.1. NEED FOR THE STUDY**

*Vrana* is the most common disease and frequently encountered problem faced in surgical practice. The knowledge of wound is known since antiquity. Meaning of vrana is “*Vrana gatra* *vichoornane*”1. *Vrana* is widely described in chapter of *Sushruta Samhita* by *Acharya Sushruta*. In ayurvedic terminology *Dushta vrana* is a wound which has *Anyatama varna*, *Puti puya srava*, G*andho-athyartam,* *Ati Vedana* and persists for longer period or takes longer period to heal.

*Acharya Sushruta* described vrana very precisely like types, subtypes*, lakshanas*2 , *Sadhy*a-*asadhyata,Vrana avastha*3*, Vrana upadrava, Vrana vasthu, Sashti upakrama4. Acharya Charaka* explained *Vrananubandha dosha*5 (Factors which impedes healing). *Dushta vrana* can be correlated with Non healing Ulcer.

An ulcer is a discontinuity of the skin or mucous membrane which occurs due to microscopic death of the tissues.

According to the study conducted on 2021 the global prevalence of wound is estimated as 6 million6. In India the study conducted by An Indian Community-based epidemiological study of wounds7 it was reported as 4.5%.

In classics different formulations are explained in the treatment of *Dushta vrana*. Which includes *Shasti Upakrama* explained by *Acharya Sushruta, Acharya Charaka* mentioned 36 proceddures8 the management of *vrana*, *Sapta vidha chikitsa*9 by *Acharya Vagbhata,* *Bhavaprakasha, Yogaratnakara* and *Sharangadhara* mentioned different remedies like *Choorna,* *Kvatha, Lepa* having *Vrana Shodhana* properties. Among them *Avachoornana*10is one of the important procedures explained in *Vrana Chikitsa* where fine powder of drugs is dusted over the affected part or wound site.

Ayurveda advocates large number of drugs and formulations for the management of vrana. Many drugs are mentioned for *Avachoornana* like *Dhataki*, *Nirgundi*, *Aragwadha*. *Kaseesadi Avachoornana*11is mentioned by *Acharya* *Sushruta* in management of *Vrana*. Hence an attempt is made to see the probable mode of action and effect of the *Kaseesadi Avachoornana* in the management of *Dushta vrana.*

**6.2. REVIEW OF LITERATURE:**

**1. DISEASE REVIEW:**

* *Nidana* of *vrana* is mentioned in *Sushrut Samhita Chikitsa Sthana*12*, Charaka Samhita Chikitsa Sthana*13*, Ashtanga Sangraha Uttara Tantra.*
* *Lakshana* of *Dushta vrana* is mentioned in *Sushrut Samhita Sutra Sthana, Ashtanga Sangraha Uttara tantra.*

* The *Chikitsa* of *Dushta vrana* is mentioned in *Charak Samhita Sutra Sthana, Sushruta Samhita Sutra Sthana, Chikitsa Sthana, Ashtanga Hrudaya Uttara Tantra, Bhela Samhita, Bhavaprakasha.*

**DESCRIPTION OF NON-HEALING ULCER:**

* An ulcer is a discontinuity of the skin or mucous membrane which occurs due to microscopic death of the tissues.
* Non healing ulcer is that persist despite appropriate care and do not proceed towards healing in a defined period with an underlying etiology.
* A Comprehensive description of non-healing ulcer, including its definition, etiopathogenesis, clinical features, investigations and treatment are explained in A concise textbook of surgery by S. Das, SRB’s Manual of Surgery and Manipal Manual of Surgery.

**DRUG REVIEW:**

* The description of *Kaseesadi choorna* in management of *Dushta vrana* is mentioned in *Sushruta Samhita Sutra Sthana.*
* All the drugs mentioned in *Kaseesadi Avachoornana* are having properties of *Vranahara, Prameha hara, Kandughna,* and *Krimighna.*

***KINVA*:**

* *Kinva* or *Surabjia* is the solid lower portion of the fermented material.
* According to *Ayurveda soukhyam*

“*Kinvakam vata shamanam”*

* *Kinva* alleviates *Vata* and having *Guru* property.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SL. NO | Drug | *Latin Name/ English Name/*  *Family* | *Rasa* | *Guna* | *Veerya* | *Vipaka* | *Part*  *Used* | *Doshaghnata & Karma* |
| 01 | *Shodita Kaseesa* | Ferrous Sulphate | *Tikta*  *Amla*  *Kashaya*  *Kshariya* | *Snigdha*  *Ushna*  *Guru*  *Nirmala*  *Dhumabha* | *Ushna* | *-* | *-* | *Vatakaphahara*  *Vranaghna* |
| 02 | *Saindhava lavana* | *Sodium chloride* | *Lavana*  *Madhura* | *Laghu*  *Snigdha* | *Sheeta* | *Madhura* | *-* | *Tridoshaghna*  *Vranahara* |
| 03 | *Vacha* | *Acorus calamus,*  *Araecea* | *Katu*  *Tikta* | *Laghu,*  *Tikshna* | *Ushna* | *Katu* | *Kanda* | *Kaphavatashamak,*  *Medhya* |
| 04 | *Haridra* | *Curcuma longa,*  *Zingiberecae* | *Tikta*  *Katu* | *Ruksha*  *Laghu* | *Ushna* | *Katu* | *Kanda* | *Vata Kapha hara*  *Prameha hara*  *Vrana hara*  *Krimighna*  *Kandughna* |
| 05 | *Daruharidra* | *Berberis aristate,*  *Berberidaceae* | *Tikta* | *Laghu*  *Ruksha* | *Ushna* | *Katu* | *Khanda* | *Kapha Pitta hara*  *Kandughna*  *Vranahara* |

**6.3. PREVIOUS RESEARCH WORK:**

* Dane P R. A Comparative Study of Dhataki Choorna Avachoornana in The Management of Dushta-Vrana. Shalya Tantra. Shri Radhakisan Toshniwal Ayurved Mahavidyalaya, Akola . 2006
* Anoop Ajit . Role Of Aragwadha Avachoornana in The Management of Dushta Vrana. Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan. 2015
* Surwade Veena. To Study the Shodhana Effect of Dhataki Choorna Avachoornana in Dushta Vrana. SMBT Ayurved College and Hospital, Igatpuri, Nashik. 1996
* Chavan Avinash S . To Study the Effect of Nirgundi Choorna Avachoornana on Pramehaja Vrana i.e., Diabetic Wounds. SMBT Ayurved College & Hospital, Igatpuri, Nashik . 2005

**6.4. AIMS AND OBJECTIVES:**

* To evaluate the effect of *Kaseesadi Avachoornana* in the management of *Dushta vrana* w.s.r to Non-Healing Ulcer.
* To compare the effect of *Kaseesadi Avachoornana* and *Aragwadha* *Avachoornana* in the management of *Dushta vrana* w.s.r to Non-Healing Ulcer.

**6.5. HYPOTHESIS:**

**NULL HYPOTHESIS:**

**H0**- *Kaseesadi Avachoornana* is not effective in the management of *Dushta Vrana* w.s.r to Non-Healing Ulcer.

**ALTERNATE HYPOTHESIS:**

**H1**- *Kaseesadi Avachoornana* is effective in the management of *Dushta Vrana* w.s.r to Non-Healing Ulcer.

**H2-** *Kaseesadi Avachoornana* is more effective than *Aragwadha Avachoornana* in the management of *Dushta vrana* w.s.r to Non-Healing Ulcer.

**H3**- *Kaseesadi Avachoornana* is less effective than *Aragwadha Avachoornana* in the management of *Dushta vrana* w.s.r to Non-Healing Ulcer.

**H4**- *Kaseesadi Avachoornana* and *Aragwadha Avachoornana* are equally effective in the management of *Dushta vrana* w.s.r to Non healing Ulcer.

**7. MATERIAL AND METHODS**

**7.1 MATERIALS:**

**SOURCE OF DATA**

1. **LITERARY SOURCE:**

* All relevant *Ayurvedic* and Modern literatures textbooks regarding the disease and treatment will be reviewed and documented for the study.
* Relevant research articles, journals.

1. **SAMPLE SOURCE:**

Subjects fulfilling the inclusion criteria will be selected randomly from the OPD/IPD of Shalya Tantra and Medical camps organized by Padma Ayurveda Hospital & Research Centre, Terdal.

**C. DRUG SOURCE:**

Raw drugs will be collected from herbal garden or local market and its proper Identification and Authentication will be done in *Dravya Guna* Department. *Kaseesadi choorna and Aragwadha Choorna* will be prepared by classical reference in department of *Rasa shastra* and *Bhaishajya Kalpana* SDMT’s AMC, Terdal.

**7.2. METHODS OF COLLECTION OF DATA:**

Patients irrespective of gender, religion, socio-economic status, place, who are presented with classical sign and symptoms of *Dushta vrana,* will be selected for study.

**Study design**- A Randomised Comparative Clinical Study between two groups.

**Sample size –** 40

**SELECTION CRITERIA:**

**DIAGNOSTIC CRITERIA**

The diagnosis is based on subjective and objective criteria.

**A. INCLUSION CRITERIA:**

* Patient between Age group of 30 to 60 years.
* Wounds of first and second grade as per Wagner’s classification.
* Wound associated with mild to moderate discharge.

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**B. EXCLUSION CRITERIA:**

* Wound of third, fourth and fifth grade as per Wagner’s classification.
* Patient with immunocompromised status.
* Malignant wounds.
* Wounds involving deep muscles and bony tissue.
* Wound associated with foul smell and Profuse discharge.

**C.WITHDRAWAL CRITERIA:**

During treatment if any serious condition or serious adverse effect occurs and patient not following the instructions or patient herself wants to withdraw from the study such patients may be withdrawn from the study.

**DROP-OUTS**

An attempt shall be made to record the reason for dropouts, if any during the clinical trial.

**D. INVESTIGATIONS**

* CBC
* CT-BT
* Serum Creatinine
* RBS
* HbA1c (If necessary)
* HbsAG & HIV (If necessary)

**RESEARCH/STUDY DESIGN:**

**METHODOLOGY:**

Enrolment of the 40 subjects, for the comparative clinical study with pre and post-test criteria. Consent will be taken, then screening of the subject is done and the data will be recorded specially in two group prepared case report form with a complete history, examination, necessary assessments.

|  |  |  |
| --- | --- | --- |
| SL.  NO | Group | Drug |
| 1 | Trial Group (A) | *Kaseesadi Choorna* |
| 2 | Control Group (B) | *Aragwadha Choorna* |

**INTERVENTION**

|  |  |  |
| --- | --- | --- |
| Subject | Group A | Group B |
| Route | External | External |
| Sample Size | 20 | 20 |
| Medicine | *Kaseesadi choorna* | *Aragwadha Choorna* |
| Dose | Based on wound size | Based on wound size |
| Duration of the intervention | Alternate day for 1 month | Alternate day for 1 month |
| Assessment will be done on | 0th, 7th, 14th, 28th day | 0th, 7th, 14th, 28th day |
| Follow up | 7th, 14th, 28th day | 7th, 14th, 28th day |

**PROCEDURE:**

* Procedure will be explained to the patient.
* Informed written consent will be taken.
* Patient is asked to sit in comfortable position.
* Examination of *vrana* will be done.
* Under all aseptic precautions, wash the wound with normal saline, cleaning of the wound followed by dusting of *Choorna* over the wound site.
* Appropriate Bandaging will be done.

**ADVERSE DRUG REACTION:**

* If there is any ill effect of drug during treatment it will be stopped administering immediately and patient will be treated according to symptoms.
* An attempt shall be made to know the cause of adverse reaction and will be recorded during clinical trial and same will be informed to ethical committee.

**E) ASSESSMENT CRITERIA**

Assessment will be done on the basis of subjective and objective criteria.

**SUBJECTIVE CRITERIA14**

* *Vedana* (Pain)
* *Daha* (Burning sensation)
* *Kandu* (Itching sensation)

**OBJECTIVE CRITERIA**

* Size of the wound
* *Vrana srava* (Discharge)
* *Vrana Gandha* (Smell)

**F) ASSESSMENT PARAMETERS15**

**SUBJECTIVE PARAMETER:-**

1. ***Vedana* (Pain):**

|  |  |
| --- | --- |
| Grade | Pain |
| 0 | No pain |
| 1 | Mild localised pain during movement |
| 2 | Moderate Localised pain during rest |
| 3 | Severe Continuous pain |

1. ***Daha* (Burning sensation)**

|  |  |
| --- | --- |
| Grade | Burning sensation |
| 0 | No |
| 1 | Mild Less localised |
| 2 | Moderate More localised |
| 3 | Severe Continuous burning with disturbed sleep |

1. ***Kandu* (Itching sensation):**

|  |  |
| --- | --- |
| Grade | Itching sensation |
| 0 | Absent |
| 1 | Mild localised |
| 2 | Moderate itching |
| 3 | Severe Continuous itching with disturbed sleep |

**OBJECTIVE PARAMETER**

1. **Size of the wound**

|  |  |
| --- | --- |
| Grade | Size of the wound |
| 0 | Healed |
| 1 | Small (Up to 4\*4 cm) |
| 2 | Moderate(6\*6cm) |
| 3 | More than 8\*8cm |

1. ***Vrana srava* ( Discharge)**

|  |  |
| --- | --- |
| Grade | Srava |
| 0 | No discharge |
| 1 | Less discharge |
| 2 | Profuse discharge |

**3. *Vrana Gandha***

|  |  |
| --- | --- |
| Grade | Gandha |
| 0 | No smell |
| 1 | Foul smell |

**Statistical Analysis:**

Data will be collected using case report form (CRF) designed by incorporating all aspects (Ayurveda and modern science) for the study. Such collected data will be tabulated and analysed using SPSS (Statistical package for social sciences) version 20 by using appropriate statistical test. Demographic data and other relevant information will be analyzed with descriptive statistics. Continuous data will be expressed in mean +/- standard deviation, and nominal and ordinal data will be expressed in percentage. Nominal & ordinal data will be analyzed using nonparametric tests like Friedman’s test, Wilcoxon’s signed rank test, Chi-square test. Continuous data will be analyzed using parametric test like repeated measure ANOVA, Paired-t/ Unpaired-t test, as and when required. The changes (one tailed) with p value < 0.05 will be considered as statistically significant.

**7.3 Does the study require any investigations or interventions conducted on animals, patients or humans? (If so, describe briefly)**

**YES**, the study requires interventions to be conducted on patient. No animal experiment will be carried out.

**7.4. Has ethical clearance been obtained from your institution in case of 7.3?**

**YES**, Ethical clearance obtained from Ethical Committee, SDM Trusts *Ayurvedic* Medical College & Hospital, Terdal for the above said clinical trial.

**8. LIST OF REFERENCES:**

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2. Vaidya Kaviraj Ambikadutta Shastri, Sushruta Samhita Part 1, Reprint Edition- 2019,

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4. Gupta, N., Gupta, S. K., Shukla, V. K., & Singh, S. P. (2004). An Indian community-based epidemiological study of wounds. Journal of wound care, 13(8), 323–325.

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Prakashan Varanasi, Uttara Tantra 25/40, Page.no-741.

1. Vaidya Gupta Kaviraj Atridev, Ashtanga Hrudaya, Reprint Edition- 2011, Chaukambha Prakashan Varanasi, Uttara Tantra 25/59, Page.no- 740.
2. Vaidya Kaviraj Ambikadutta Shastri, Sushruta Samhita Part 1, Reprint Edition- 2019,

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2. Rishu Kumar Sharma Et AL: Management Of Dushta Vrana By Jatyadi Ghrita Followed

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March 2017} Available from: http://www.iamj.in/posts/images/upload/782\_793.

|  |  |  |
| --- | --- | --- |
| **9. SIGNATURE OF THE**  **CANDIDATE** | **:** |  |
| **10. REMARKS OF THE**  **GUIDE** | **:** |  |
| **10.1 NAME AND**  **DESIGNATION**  **OF THE GUIDE** | **:** | **DR. ISHWAR KATTEWADIM.S(AYU)** PROFESSOR  DEPARTMENT OF SHALYA TANTRA  S.D.M. TRUST’S AYURVEDIC MEDICAL COLLEGE, DANIGOND POST-GRADUATION CENTRE, PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE,  TERDAL-587315 |
| **10.2 SIGNATURE** | **:** |  |
| **10.3 NAME AND DESIGNATION**  **OF THE CO-GUIDE** | **:** | **DR. SHRIDHAR WADDAR M.S(AYU)**  ASSISTANT. PROFESSOR DEPARTMENT OF SHALYA TANTRA  S.D.M. TRUST’S AYURVDIC MEDICAL COLLEGE, DANIGOND POST-GRADUATION CENTRE, PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE,  TERDAL-587315 |
| **10.4 SIGNATURE :** |  |  |
| **11.1 HEAD OF THE DEPARTMENT** | **:** | **Dr. S.L.BALARADDIM.S.(AYU)**  PROFESSOR AND HOD,  DEPARTMENT OF SHALYA TANTRA  S.D.M. TRUST’S AYURVEDIC MEDICAL COLLEGE, DANIGOND POST-GRADUATION CENTRE,  PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE,  TERDAL-587315 |
| **11.2 SIGNATURE** | **:** |  |
| **12.1 REMARKS OF THE**  **PRINCIPAL** | **:** |  |
| **12.2 PRINCIPAL** | **:** | **Dr. PRABHAKAR.B. APARAJ**  **M.D.(AYU) Ph.D. (SCHOLAR)**  S.D.M. TRUST’S AYURVEDIC MEDICAL COLLEGE, DANIGOND POST-GRADUATION CENTRE, PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE,  TERDAL-587315 |
| **12.3 SIGNATURE** | **:** |  |