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



COMPLETED PROFORMA FOR REGISTRATION OF SUBJECT

FOR DISSERTATION IN M.S.(AYURVEDA)

**TOPIC**

**“RANDOMISED CONTROL TRIAL TO EVALUATE THE EFFECT OF KASEESADI AVACHOORNANA AND ARAGWADHA AVACHOORNANA IN MANAGEMENT OF DUSTA VRANA W.S.R TO NON-HEALING WOUND(ULCER)”**

**BY**

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IST YEAR P.G SCHOLAR,

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**GUIDE**

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**NAME OF THE INSTITUTE**

**SDM TRUST’S**

**AYURVEDIC MEDICAL COLLEGE,**

**DANIGOND POST GRADUATION CENTRE,**

**PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTER,**

**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

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Terdal-587315, Karnataka

**TO,**

**THE REGISTRAR**

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES,

BANGALURU, KARNATAKA.

**THROUGH,**

THE PRINCIPAL AND H.O.D OF THE DEPARTMENT OF SHALYA TANTRA.

SDM Trust’sAyurvedic Medical College,

Danigond Post-Graduation Center,

Padma Ayurvedic Hospital and Research Center,

Terdal-587315, Karnataka.

Respected Sir/Madam,

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

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 for the award of the degree M.S (Ayurveda) in SHALYA TANTRA.

**TITLE:**

**“RANDOMISED CONTROL TRIAL TO EVALUATE THE EFFECT OF KASEESADI AVACHOORNANA AND ARAGWADHA AVACHOORNANA IN MANAGEMENT OF DUSTA VRANA W.S.R TO NON-HEALING WOUND ( ULCER)”**

Here with, I am enclosing the completed Proforma for the registration of the dissertation subject*.*

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  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(AYU), SHALYA TANTRA |
| **4. DATE OF THE ADMISSION OF COURSE** | : | 27 APRIL 2023 |
| **5. NAME OF THE TOPIC** | : |  |
| **“RANDOMISED CONTROL TRIAL TO EVALUATE THE EFFECT OF KASEESADI AVACHOORNANA AND ARAGWADHA AVACHOORNANA IN MANAGEMENT OF DUSTA VRANA W.S.R TO NON-HEALING WOUND(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 Shalya tantra by *Acharya Sushruta*. In ayurvedic terminology *Dushta vrana*2 is a wound which has anyatama varna, *puti puya srava*, *gandho-athyartam,* *ati Vedana* and persists for longer period or takes longer period to heal.

*Acharya Sushruta* described vrana very precisely like types, subtypes*, lakshanas*3, *sadhy*a-*asadhyata3, vrana avastha, 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 wound6 is estimated nearly 6 million people suffer from wounds worldwide. In India the study conducted by An Indian Community-based epidemiological study of wounds7 it was reported as 4.5% 1000 population.

In classics different formulations are explained in the treatment of *Dushta vrana*. Which includes *Shasti Upakrama* explained by *Acharya Sushruta, Acharya Charaka* mentioned 36 procedures8 the management of vrana, Saptopakrama chikitsa10 by *acharya Vagbhata*10*,* *Bhavaprakasha, Yogaratnakara* and *sharangadhara* mentioned different remedies like *churna,* *kvatha, lepa* having *vrana shodhana* properties. Among them *Avachoornana*11is one of the procedure 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 Avachoornana12 is 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*13*, Charaka Samhita Chikitsa Sthana*14*, Ashtanga Sangraha Uttara Tantra*15*.*
* *Lakshana* of *Dushta vrana* is mentioned in
* The *Chikitsa* of Dushta vranais mentioned in *Charak Samhita Sutra Sthana*17*, Sushrut Samhita Sutra Sthana*18*, Chikitsa Sthana*19*, Ashtanga Hrudaya Uttara Tantra*20*, Bhela Samhita*21*, Bhavaprakasha*22*.*

**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.
* 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 REVIEW20:**

* 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, Krimighna.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SL. NO | Drug name | *Latin Name* | *Rasa* | *Guna* | | *Veerya* | *Vipaka* | *Part*  *Used* | *Doshaghnata & Karma* |
| 01 | *Kaseesa* | Ferrous Sulphate | Tikta  Amla  Kashaya  Kshariya | Snigdha  Ushna  Guru  Nirmala  Dhumabha | | Ushna | - | *-* | Vranaghna  Vatakaphahara |
| 02 | *Saindhava lavana* | *Sodium chloride* | *Lavana*  *Madhura anurasa* | | *Laghu*  *Snigdha* | *Sheeta* | *Madhura* | *-* | *Tridoshagnha*  *Vranahara* |
| 03 | *Kinva* |  |  |  | |  |  |  |  |
| 04 | *Vacha* | *Acorus calamus,*  *Araecea* | *Katu*  *Tikta* | *Laghu,*  *Tikshna* | | *Ushna* | *Katu* | *Kanda*  (Rhizome) | *Kaphavatashamak,*  *Medhya* |
| 05 | *Haridra* | *Curcuma longa,*  *Zingiberecae* | *Tikta*  *Katu* | *Ruksha*  *Laghu* | | *Ushna* | *Katu* | *Kanda* | *Prameha hara*  *Vrana hara*  *Krimighna*  *Kandughna* |
| O6 | *Daruharidra* | *Berberis aristate* | *Tikta* | *Laghu*  *Ruksha* | | *Ushna* | *Katu* | *Kanda* | *Netrya*  *Kandughna*  *Vranahara* |

**KINVA:**

Kinva or surabjia is the solid lower portion of the fermented material.

According to Ayurveda soukhyam

“*Kinvakam vata shamanam”*23

*Kinva* alleviates vata and having Guru property.

**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 Kasesadi 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**- Both *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**- Comparative clinical study.

**Sample size –** 40

**SELECTION CRITERIA:**

**DIAGNOSTIC CRITERIA**

The diagnosis is based on subjective and objective criteria.

1. Subjective:

* Pain
* Burning sensation
* Itching

1. Objective:

* Size of the ulcer
* Discharge
* Foul smell

**A. INCLUSION CRITERIA:**

* Wounds of first and Second grade.
* Wound associated with less discharge.
* Wound associated with foul smell.
* Patient between Age group of 30 to 50 yrs.

**B. EXCLUSION CRITERIA:**

* Wound of third and fourth grade.
* Patient with immunocompromised status.
* Wound associated with bone involvement.
* Hyper granulation tissue.

**C.WITHDRAWAL CRITERIA:**

During the course of 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**

* RBS
* HbA1c

**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 and necessary assessments.

|  |  |  |
| --- | --- | --- |
| SL.  NO | Group | Drug |
| 1 | Control group(A) | Aragwadha choorna |
| 2 | Trail group(B) | Kaseesadi choorna |

**INTERVENTION**

|  |  |  |
| --- | --- | --- |
| Route | External | External |
| Sample size | 20 | 20 |
| Medicine | Kaseesadi choorna | Aragwadha choorna |
| Dose | Based on wound size | Based on wound size |
| Duration of drug intervention | Once per day ,1 month | Once per day, 1 month |
| Assessment will be done on | 0th,7th,14th,21st,28th,35th days | 0th,7th,14th,21st,28th,35th days |
| Follow up |  |  |

**PROCEDURE:**

* Procedure should be explained to the patient.
* Take consent.
* Patient is asked to sit in comfortable position.
* Inspection of vrana should 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.
* Bandaging should 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 CRITERIA**

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

**OBJECTIVE CRITERIA**

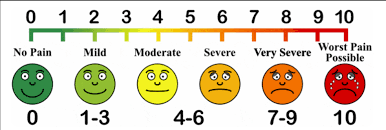
* Size of the wound
* Vrana srava (Discharge)
* Vrana Gandha (Smell)

**F) ASSESSMENT PARAMETERS**

As per the REALISE SCORE questionnaire,

**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 burning sensation |
| 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 | Up to 4\*4 centimetre |
| 2 | Up to 6\*6 centimetre |
| 3 | More than 8\*8 centimetre |

1. **Vrana srava ( Discharge)**

|  |  |
| --- | --- |
| Grade | Type of Srava |
| 0 | No discharge |
| 1 | Mild Scanty discharge |
| 2 | Moderate Discharge associate with blood |
| 3 | Severe Profuse and continuous discharge |

**3. Vrana Gandha**

|  |  |
| --- | --- |
| Grade | Type of Gandha |
| 0 | No smell |
| 1 | Mild Foul smell |
| 2 | Moderate Unpleasant |
| 3 | Foul smell which is intolerable |

**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 patients or human subjects. No animal experiment will be carried out.

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

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

**8. LIST OF REFERENCES:**

|  |  |  |
| --- | --- | --- |
| **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 BALARADDI (M 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** | **:** |  |