

**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

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**1ST YEAR P.G SCHOLAR,
DEPT. OF P.G STUDIES IN SHALYA TANTRA**

GUIDE

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NAME OF THE INSTITUTE

SDM TRUST'S

**AYURVEDIC MEDICAL COLLEGE,
DANIGOND POST GRADUATION CENTRE,
PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE,
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2021-2022

FROM,

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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

Date: 27/09/2023

Yours's faithfully
(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
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- 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 COMAPATIVE 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*, *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*², *Sadhya-asadhyata*, *Vrana avastha*³, *Vrana upadrava*, *Vrana vasthu*, *Sashti upakrama*⁴. *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 procedures⁸ the management of *vrana*, *Sapta vidha chikitsa*⁹ by *Acharya Vagbhata*, *Bhavaprakasha*, *Yogaratanakara* and *Sharangadhara* mentioned different remedies like *Choorna*, *Kvatha*, *Lepa* having *Vrana Shodhana* properties. Among them *Avachoornana*¹⁰ is 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*¹¹ 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*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	<i>Shodita Kaseesa</i>	Ferrous Sulphate	<i>Tikta Amla Kashaya Kshariya</i>	<i>Snigdha Ushna Guru Nirmala Dhumabha</i>	<i>Ushna</i>	-	-	<i>Vatakapahara Vranaghna</i>
02	<i>Saindhava lavana</i>	<i>Sodium chloride</i>	<i>Lavana Madhura</i>	<i>Laghu Snigdha</i>	<i>Sheeta</i>	<i>Madhura</i>	-	<i>Tridoshaghna Vranahara</i>
03	<i>Vacha</i>	<i>Acorus calamus, Araecea</i>	<i>Katu Tikta</i>	<i>Laghu, Tikshna</i>	<i>Ushna</i>	<i>Katu</i>	<i>Kanda</i>	<i>Kaphavatashamak, Medhya</i>
04	<i>Haridra</i>	<i>Curcuma longa, Zingiberaceae</i>	<i>Tikta Katu</i>	<i>Ruksha Laghu</i>	<i>Ushna</i>	<i>Katu</i>	<i>Kanda</i>	<i>Vata Kapha hara Prameha hara Vrana hara Krimighna Kandughna</i>
05	<i>Daruharidra</i>	<i>Berberis aristata, Berberidaceae</i>	<i>Tikta</i>	<i>Laghu Ruksha</i>	<i>Ushna</i>	<i>Katu</i>	<i>Khand a</i>	<i>Kapha Pitta hara Kandughna Vranahara</i>

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

A. 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.

B. 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.

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)	<i>Kaseesadi Choorna</i>
2	Control Group (B)	<i>Aragwadha Choorna</i>

INTERVENTION

Subject	Group A	Group B
Route	External	External
Sample Size	20	20
Medicine	<i>Kaseesadi choorna</i>	<i>Aragwadha Choorna</i>
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	0 th , 7 th , 14 th , 28 th day	0 th , 7 th , 14 th , 28 th day
Follow up	7 th , 14 th , 28 th day	7 th , 14 th , 28 th 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

2. *Daha* (Burning sensation)

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

3. *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

2. *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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13. Vaidya Sastri Sri Satya Narayana, Caraka Samhita of Agnivesa revised by Caraka, Drdabala, Hindi Commentary by Kasinatha Sastri, Dr Gorakhanatha Chaturvedi, Reprint-2018, Chaukhambha Visvabharati Varanasi, Chikitsa Sthana 25/7,8 , Page.no-618.
14. Rishu Kumar Sharma Et AL: Management Of Dushta Vrana By Jatyadi Ghrita Followed By Jalaukavacharna. *International Ayurvedic Medical Journal* {online}2017 {cited March 2017} Available from: http://www.iamj.in/posts/images/upload/782_793.p
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9. SIGNATURE OF THE CANDIDATE	:
10. REMARKS OF THE GUIDE	:
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10.4 SIGNATURE	:

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