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Research Protocol

Ayurveda Section

Evaluation of Comparative Efficacy of *Arjunadi* Ointment versus Cadexomer Iodine Ointment on Wound Healing of *Madhumehjanya Dushta Vrana* (Diabetic Foot Ulcer): A Clinical Trial Protocol

SHUBHAM BHAGWAN PATIL[1], SHEETAL ASUTKAR[2]

ABSTRACT

Introduction: Diabetic foot ulcers are one of the most common complications associated with diabetes and are linked to poor glycaemic control, peripheral neuropathy, and vascular disease. Chronic wounds, most often found on the soles of the feet, are the leading cause of lower extremity amputations globally. Traditional treatments primarily focus on infection control and wound closure but often fail to address the complex physiological and pathological processes involved in healing. The present randomised, single-blind, double-arm clinical study compares the effectiveness of *Arjunadi* ointment, a polyherbal formulation from Ayurveda, with that of Cadexomer iodine ointment in managing diabetic foot ulcers.

Aim: To compare the efficacy of *Arjunadi* and Cadexomer iodine ointments in diabetic foot ulcer healing, integrating Ayurvedic principles with modern clinical methods for comprehensive management.

Need of the study: Diabetic foot ulcers affect nearly 15% of individuals with diabetes, often leading to complications such as infections, osteomyelitis, and amputations. While conventional treatments primarily target infection control, other aspects of wound care remain unmet. *Arjunadi* ointment offers a holistic healing approach with anti-inflammatory, antimicrobial, and analgesic properties.

Materials and Methods: The present randomised, single-blind, double-arm trial will take place in the outpatient and inpatient Departments of *Shalya Tantra* at Mahatma Gandhi Ayurveda Hospital, Wardha, Maharashtra, India. The study will include 30 participants aged 30-70 years with chronic diabetic nonhealing foot ulcers persisting for over four weeks. The study is expected to commence in February 2026. Participants are divided into two groups: Group A, treated with Cadexomer iodine ointment, and Group B, treated with *Arjunadi* ointment. Ointments will be applied twice daily for 30 days, supplemented with standard antidiabetic drugs and antibiotics. Wound healing is evaluated on days 0, 15, and 30 using the Bates-Jensen Wound Assessment Scale (BJWAS). Statistical analysis, including paired and unpaired t-tests, will determine treatment efficacy. The study trial lasts three months, including a follow-up evaluation on the 60th day after treatment.

Keywords: Chronic wounds, Diabetic complications, Herbal medicine, Skin ulcer, Wound healing

INTRODUCTION

A common and frequently encountered problem in day-to-day medical practice is *Dushta Vrana*, or chronic wounds/ulcers [1]. Wound healing continues to pose a significant challenge in surgical practice, often complicated by infection, which makes the healing process difficult and delayed. In Ayurveda, the scope of *Shalya Tantra*, or surgical science, prominently includes the management of *Vrana* or wounds [2]. As Acharya Sushruta, the father of surgery, states,

वृणोतियस्माद्रूढेऽपिव्रणवस्तुननश्यति ॥

आदेहधारणात्तस्माद्व्रणइत्युच्यतेबुधैः ।

"This shloka highlights that even after a wound is fully healed, it leaves a scar, symbolising its permanent imprint on the body." The term "*Vrana*" is derived from its ability to cause tissue destruction or damage to a part of the body, necessitating adequate management for optimal recovery [3,4].

Dushta Vrana can adversely affect a patient's health, leading to various complications that may become fatal if, left untreated. Slough, infection, and foreign bodies hinder the normal healing process. Conversely, a clean and healthy wound heals more efficiently. This emphasises the need to keep wounds uncontaminated throughout all stages of healing [5,6].

Acharya Sushruta exhaustively categorised *Dushta Vrana* into six types and delineated their management using two broad categories of drugs: *Vranashodhana* (cleansing agents) and *Vranaropana* (healing agents). Many of these agents exhibit the properties of *Katu* (pungent), *Tikta* (bitter), *Madhura* (sweet), and *Kashaya* (astringent) rasa, making them particularly suitable for wound management. Wound healing is a natural process; however, it can be disturbed by deranged *Doshas* (Ayurvedic humors). Therefore, managing *Dushta Vrana* requires a multipronged approach involving cleansing, detoxification, and rejuvenation [7,8].

Arjunadi Ointment

Arjunadi ointment is a polyherbal formulation based on Ayurvedic principles. It contains Terminalia arjuna (*Arjuna*), Aloe Vera, Psoralea corylifolia (*Bakuchi*), Rubia cordifolia (*Manjishtha*), and Curcuma longa (*Haridra*). These herbs are well known for their anti-inflammatory, antimicrobial, analgesic, and wound-healing properties. This ointment cleans the wound, reduces inflammation, and promotes tissue regeneration, making it suitable for managing *Dushta Vrana* or diabetic foot ulcers [9].

Cadexomer Iodine Ointment

Cadexomer iodine is a standard wound care product widely used for its antimicrobial properties. It can absorb exudates, kill bacteria,

and promote a moist environment that facilitates the healing process. However, it primarily focuses on infection control rather than the comprehensive healing properties offered by the polyherbal formulation found in *Arjunadi* ointment [10].

Dushta Vrana and Wound Healing

The management of *Dushta Vrana* requires a holistic approach that addresses the root causes of delayed healing. Ayurveda explains that deranged *Vata* and *Pitta Doshas* are often associated with nonhealing wounds. Therefore, medications possessing *Amapachaka* (toxin-digesting), *Tridoshahara* (balancing all three Doshas), and *Krimihara* (antimicrobial) properties are very important [11].

Ayurvedic management consists of two main phases: *Shodhana Chikitsa* (cleansing therapy), which includes detoxifying the wound with agents that clear slough, decrease infection, and reduce symptoms such as foul odor, itching, and pain; and *Ropana Chikitsa* (healing therapy), where healing agents are applied after cleansing to stimulate granulation and epithelialisation, ensuring complete recovery [12].

Acharya Sushruta also emphasised the importance of adequately assessing the wound, including the type of ulcer, the extent of *Dushti* (contamination), and the involvement of body tissues (*Dhatus*). Modern science supports this principle, as effective wound healing requires care that is tailored to the characteristics of the wound [13].

Aim

The present study compares the efficacy of *Arjunadi* ointment with Cadexomer iodine ointment in managing diabetic foot ulcers, which are similar to *Madhumehjanya Dushta Vrana* in Ayurveda. Although Cadexomer iodine has superior infection control, *Arjunadi* ointment offers a more holistic approach that provides both antimicrobial action and tissue repair and regeneration.

REVIEW OF LITERATURE

Diabetic Foot Ulcers (DFUs) are a significant complication of diabetes, primarily leading to infections, amputations, and a reduction in the quality of life. Effective management of DFUs is essential for minimizing these outcomes. Among the treatments, two of the most promising options are *Arjunadi* ointment and Cadexomer iodine ointment. *Arjunadi* ointment is a polyherbal Ayurvedic formulation containing herbs such as Terminalia arjuna, Aloe Vera, and Psoralea corylifolia, which have been reported to possess wound-healing, anti-inflammatory, and antimicrobial activities [14]. This formulation addresses multiple facets of wound healing, including reducing microbial load, promoting tissue regeneration, and alleviating inflammation, thereby offering a holistic therapeutic approach.

Conversely, Cadexomer iodine is a topical antimicrobial dressing for chronic wounds. It slowly releases iodine to control infection, absorbs wound exudates, and promotes debridement. Numerous clinical trials have demonstrated its potential for reducing the size of ulcers and promoting healing, especially in cases of infected or chronic wounds. Both treatments are effective; however, *Arjunadi* ointment focuses on holistic wound management, combining cleansing, antimicrobial, and healing properties, while Cadexomer iodine centers on infection control and moisture balance. Comparative studies of these ointments could facilitate further integration of Ayurvedic and conventional treatments to enhance the management of DFUs, promoting faster and more holistic healing [15].

The DFUs, as a significant complication of diabetes, often develop microbial biofilms that delay healing. Schwartz JA et al., showed that Cadexomer iodine significantly decreases bioburden in diabetic foot ulcers and enhances wound characteristics [16]. Malone M et al., demonstrated that it can decrease microbial load and the diversity of microorganisms in wounds complicated by biofilm [17]. Roche ED et al., proved its efficacy in reducing bacterial biofilms in both clinical and experimental settings [18]. Woo K et al., supported its application alongside other treatments for chronic wounds and justified the systematic review process in this document [19]. Lastly, Malone M et al., reported a significant reduction in biofilms using two- and six-week regimens of Cadexomer iodine [20]. These studies underscore the role of Cadexomer iodine in managing diabetic foot ulcers and its potential for better outcomes, as shown in [Table/Fig-1] [16-20].

Author(s)	Title	Journal and year	Findings	Summary
Schwartz JA et al., [16]	A prospective, non comparative, multicenter study to investigate the effect of cadexomer iodine on bioburden load in diabetic foot ulcers	Int Wound J, 2013	Cadexomer iodine significantly reduced bioburden and improved wound characteristics in diabetic foot ulcers	Demonstrates the potential of cadexomer iodine to improve wound healing through infection control
Malone M et al., [17]	Effect of cadexomer iodine on the microbial load and diversity of chronic nonhealing diabe tic foot ulcers complicated by biofilm in-vivo	J Antimicrob Chemother, 2017	Reduction in microbial load and diversity in diabetic foot ulcers treated with cadexomer iodine	Highlights effectiveness in managing biofilm-related complications in chronic wounds
Roche ED et al., [18]	Cadexomer iodine effectively reduces bacterial biofilm in ex vivo and in-vivo in porcine wounds.	Int Wound J, 2019	Cadexomer iodine effectively reduced bacterial biofilm in both experimental and clinical settings.	Confirms efficacy in biofilm management, supporting clinical application.
Woo K et al., [19]	Efficacy of topical cadexomer iodine treatment in chronic wounds: Systematic review and meta-analysis of comparative clinical trials	Int Wound J, 2021	A systematic review confirmed the efficacy of cadexomer iodine in chronic wound management, improving healing outcomes	Provides comprehensive evidence of cadexomer iodine's role in improving wound healing outcomes in chronic wounds
Malone M et al., [20]	Effect on total microbial load and community composition with two vs six-week topical Cadexomer iodine for treating biofilm infections	Int Wound J, 2019	Significant biofilm reduction in diabetic foot ulcers treated with two- and six-week cadexomer iodine regimens	Demonstrates flexibility and effectiveness of cadexomer iodine regimens for chronic diabetic wound infections

[Table/Fig-1]: Summary of previous studies on cadexomer iodine in diabetic foot ulcer management [16-20].

MATERIALS AND METHODS

The present randomised, single-blind, double-arm trial will take place in the outpatient and inpatient Departments of Shalya Tantra at Mahatma Gandhi Ayurveda Hospital, Wardha, Maharashtra, India. over three months. The study is expected to commence in February 2026. Sequential participants will be enrolled individually until a total sample size of 30 is achieved and where patients will be kept blinded regarding their treatment, while the investigator will be aware of the allocation. Blinding will be achieved using identical packaging and labeling for both *Arjunadi* and Cadexomer iodine ointments. Randomisation will be based on a computer-generated sequence, with sealed envelopes used to conceal the allocation. The Institutional Ethics Committee (IEC) of DMIHER, Wardha, has approved the proposal under Reference No: MGACHRC/IEC/July–2022/568 dated 18.09.2023. The trial has been retrospectively registered with the CTRI, with registration number CTRI/2024/03/064381 dated

19.03.2024. Before enrollment, participants will provide written informed consent after being fully informed of the study's purpose, procedures, risks, and benefits. Participant confidentiality will be maintained throughout the study.

In present prospective, randomised, single-blind, two-arm clinical study, 30 patients will be enlisted and divided equally into two groups: Group A, which will receive Cadexomer iodine ointment, and Group B, which will be treated with *Arjunadi* ointment. Both ointments will be applied topically twice daily for 30 days.

Participants in present study will be selected based on specified inclusion and exclusion criteria to ensure the findings are valid, reliable, and applicable to the target population.

Inclusion criteria: Participants aged 30 to 70 years with a diagnosis of diabetic foot ulcers classified under Wagner scale grades 1 to 3 will be included in the study. The ulcers must have been present for at least four weeks, ensuring that the wounds are chronic and require therapeutic intervention. All participants must provide written informed consent, confirming their understanding of the study's purpose, procedures, risks, and benefits. These criteria aim to select patients with moderate wound severity who can be managed with the intervention under investigation.

Exclusion criteria: Exclusion criteria have been established to eliminate confounding variables that might affect the study's outcomes. Patients with diabetic foot ulcers classified as Wagner scale grades 4 and 5, which indicate severe conditions such as gangrene or exposed deep structures, or those requiring amputation, will be excluded. Additionally, systemic complications such as nephropathy, retinopathy, or neuropathy will also render a patient ineligible for the study.

Sample size calculation: The total sample size is 30, with 15 participants in each group. The sample size was computed based on the anticipated effect size and available references. Assuming clinically significant differences in wound healing outcomes between the two groups (two-tailed test at a significance level of 0.05 and a power of 80%), a sample size of 30 was considered sufficient for this phase-I trial.

Study Procedure

Patients will be randomised into two groups:

- Group A (Control group): Cadexomer iodine ointment applied topically twice daily after dressing for 30 days.
- Group B (Intervention group): *Arjunadi* ointment applied topically twice daily after dressing for 30 days.

Both groups will be allowed to continue their antidiabetic medications and systemic antibiotics if, necessary to maintain uniform systemic parameters unaffected by the nature of the treatments.

Parameters evaluated: The primary criterion evaluated will be wound healing. The BJWAS (Braden Joint Wound Assessment Scale) will measure the size and depth of wounds, tissue type, nature of exudate, and condition of surrounding skin. Follow-up assessments will be conducted on days 0, 15, 30, and 60 to monitor lasting effects.

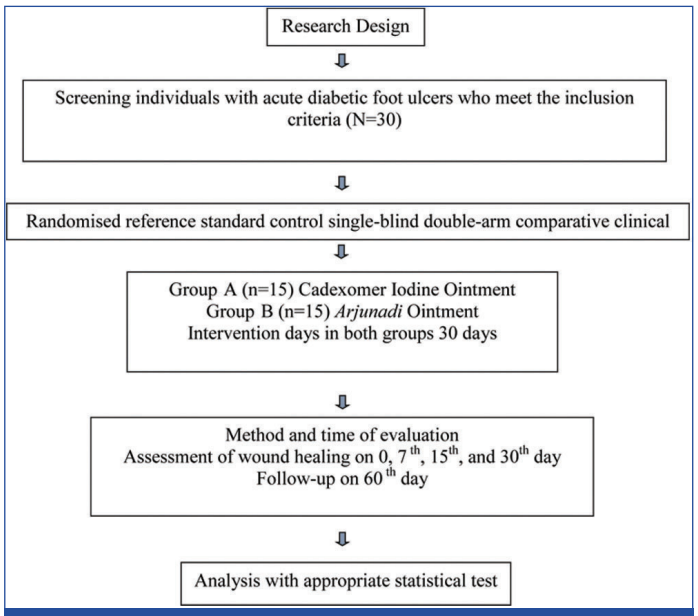
Ethical considerations: Participants will be free to withdraw from the study at any time. If, any adverse effects or illnesses occur, participants will receive appropriate medical care, and the sample size will be restored by replacing any affected participants. Data will be stored securely, and patient confidentiality will be strictly maintained throughout the study.

The details of the methodology can be found in [Table/Fig-2], while the study design is depicted in [Table/Fig-3].

Intervention description (Drug preparation): Fresh plants and plant parts of *Arjuna* (*Terminalia arjuna*), *Aloe Vera*, *Bakuchi*, *Ajan Vruksha (Khandu Chakka)*, *Shalmali*, *Haridra*, and *Manjishtha* will be collected from the campus of Mahatma Gandhi Ayurved Hospital, Wardha, and authenticated by the Department of *Dravyaguna* (Pharmacology and Materia Medica - Herbal).

Groups	Sample size	Treatment	Frequency	Treatment period	Assessment	Follow-ups
A	15	Cadexomer Iodine ointment (Standard control treatment)	Topical application twice a day following dressing	30 days	Assessment on 0, 1, 15th and 30th day	30th, 45th and 60th day
B	15	*Arjunadi* ointment (Interventional treatment)	Topical application twice a day following dressing	30 days	Assessment on 0, 1, 15th and 30th day	30th 45th and 60th day

[Table/Fig-2]: The study methodology.



[Table/Fig-3]: Trial design summary.

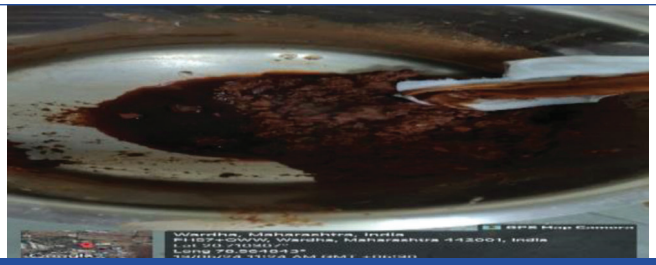
Preparation of *arjunadi* decoction extract: The decoction of *Arjunadi* extract is prepared by combining one part of fresh *Arjunadi* plants with 16 parts of water, resulting in a ratio of 1:16 of plants to water through heat. This corresponds to using 1 kg of *Arjunadi* and 16 liters of water, yielding a total quantity of two liters for the *Arjunadi* decoction extract.

Preparation of *arjunadi* paste (*Kalka*): A paste of fresh *Arjunadi* plants was created using a mortar and pestle with a small amount of water, forming a smooth paste weighing 125 mg.

Preparation of *arjunadi* ghrita (Ghee): *Arjunadi Ghrita* is formulated by combining one part paste, four parts *Ghrita*, and 16 parts decoction extract, resulting in a final proportion of 1:4 through heat. This corresponds to using 125 mg of paste, 500 mg of *Ghrita*, and two liters of decoction extract, yielding 412 mg of *Arjunadi Ghrita*.

Preparation of *arjunadi* ointment [Table/Fig-4-9]: The preparation of *Arjunadi* ointment commenced during the protocol submission phase, with 50% of the process completed. Since then, the remaining formulation and standardisation processes have been finalized, making the ointment fully ready for clinical application. The manufacturing process was carried out by Dattatray Ayurved Rasashala, a Good Manufacturing Practice (GMP)-certified Ayurvedic facility within the Mahatma Gandhi Ayurvedic College Hospital and Research Centre in Wardha. This facility operates under license number NG/AYU/002/14, which permits Ayurvedic pharmacy operations.

The ointment base was prepared with an accurate combination of ingredients, including 10% Stearic Acid, 10% Cetostearyl Alcohol, 5% Pure White Beeswax, 5% Petroleum Jelly, 30% Water, and 50% *Arjunadi Ghrita*. Preparation involved continuous trituration

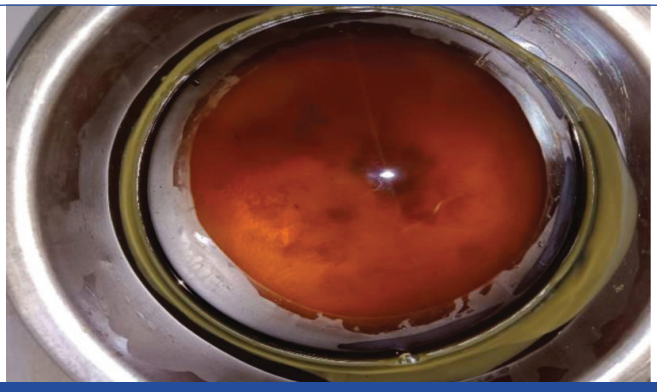


[Table/Fig-4]: Preparation of *Arjunadi Ghrita* with the initial heating and mixing of herbal ingredients to extract active components.

[Table/Fig-5]: Filtering the prepared *Arjunadi Ghrita* to remove solid residues, ensuring a clear and pure formulation.

[Table/Fig-6]: Pour the filtered *Arjunadi Ghrita* into a container for the subsequent blending phase with other ingredients.

[Table/Fig-7]: Add carrier oils into the *Arjunadi Ghrita* during the formulation process to enhance the consistency and therapeutic properties.



[Table/Fig-8]: Liquidation of the ointment base before cooling and solidification.

[Table/Fig-9]: *Arjunadi* ointment in its final creamy form.

and heating to ensure uniform consistency and stability. Batch A was selected as the final product among the prepared formulations due to its superior stability and consistency. Other batches were documented and stored for future reference, demonstrating the care taken during the standardization process.

For the control group, the ointment was obtained from Win-Medicare, an Indian pharmaceutical company known for advanced wound care solutions. The study, by partnering with a well-established Ayurvedic manufacturing facility and a leading Indian pharmaceutical company, ensures that these two treatments for diabetic foot ulcers are comprehensively compared with high-quality results.

Assessment criteria: Wound healing will be assessed using the Bates-Jensen Wound Assessment Tool (BJWAS) and the Pressure Sore Status Tool (PSST). These tools are validated instruments intended to measure wound healing at specified intervals. They grade 13 characteristics of wounds, such as size, depth, edges, undermining, type and amount of necrotic tissue, type and amount of exudate, surrounding skin color, oedema and induration of peripheral tissue, granulation tissue, and epithelialisation. Each characteristic is rated from 1 (the healthiest attribute) to 5 (the unhealthiest attribute). Higher total scores reflect worse wound conditions. The BJWAS will provide straightforward and objective monitoring of wound healing progress and the effectiveness of the interventions [21].

Variables to be Measured: Enhancements in the primary outcomes, including wound healing, are anticipated as improvements in the clinical features of diabetic foot ulcers.

Participant timeline

i. Topical application of standard control and interventional drug (twice a day for 30 days)

ii. Antidiabetic drug (twice a day for 30 days)

iii. Antibiotics if, required (twice a day for 15 days)

Enrollment in the study will follow this schedule: Patients diagnosed with diabetic foot ulcers and presenting with symptoms for more than four weeks will be eligible for enrollment.

Interventions: No washout period is incorporated; participants will receive the topical treatment for a duration of 30 days.

Assessments and Visits for Participants: Evaluations will be conducted on days 0, 7, and 15, with follow-up visits scheduled on the 30th day after the intervention.

Assignment of interventions (for controlled trials)

Patients will be enlisted through a straightforward randomisation process utilising a computer-generated table. The principal investigator and co-investigator will be responsible for the allocation and enrollment of patients.

To implement the randomisation, the researcher will generate random numbers using a computer-generated sequence, creating random allocation cards. The original random allocation sequences will be securely stored in a third-party location, and a copy will be used for practical purposes. The researcher will conduct the enrollment of patients. Envelopes used for this process will bear external serial numbers for identification. Essential details, including patient ID, post-procedure results, and other pertinent information, will be documented.

Data Collection, management, and analysis methods: A strategy involving scheduled appointment reminders and planned question-and-answer sessions will be implemented to ensure patient retention. Comprehensive follow-up records will be maintained in the patient file. In cases where patients need to withdraw or discontinue, the patient file will be formally closed and archived for record-keeping.

Upon completion of the study, observations will be gathered from the data collected using the following tools:

i. Case registration paper containing detailed history and examination;

ii. Proforma for follow-up assessment;

The principal investigator and co-investigator will be responsible for data monitoring and coding. Data entry will be executed in both computer and hard copy formats of the case record form. Values will be double-checked before being entered into the computer system. Each patient file will be secured with a specific patient code.

Outcome measures: The primary outcome measure for present study will be wound healing, as assessed by the BJWAS. This tool evaluates critical wound parameters, including size, depth, tissue type, exudate characteristics, and surrounding skin condition. Each parameter has a scoring system; therefore, the score at the end indicates the severity of the wound and the healing progress over time. These scores will be recorded on days 0, 15, and 30, with a follow-up assessment on day 60 to evaluate long-term effects. The reduction in the BJWAS score over time will determine how effective *Arjunadi* ointment is compared to Cadexomer iodine ointment. The secondary outcome measures will include the absence of complications such as infection, pain relief, and improvement in the general quality of the wound, as observed through clinical signs and symptoms.

STATISTICAL ANALYSIS

For data analysis, paired t-tests will be performed for within-group comparisons and unpaired t-tests for between-group comparisons. A significance level of $p<0.05$ will be considered significant. The analysis will emphasise changes in the wound assessment score over time and the comparative efficacy of the two treatment options. Statistical analysis for present study will be conducted using IBM Stastistical Packages of Social Sciences (SPSS) version 26.0, which is a widely used software in clinical and biomedical research. SPSS offers powerful tools for data management and statistical analysis, enabling the accuracy and reproducibility of results. Thus, it will assist in data entry, organisation, and the application of statistical tests to compare parameters between two groups [22,23]. In the statistical analysis, paired t-tests will be conducted to compare pre-treatment and post-treatment scores within each group to ascertain the improvement achieved by each intervention. The unpaired t-test will compare changes in wound healing scores between the two groups to assess the relative efficacy of *Arjunadi* ointment and Cadexomer iodine ointment. Descriptive statistics, including means, standard deviations, and percentages, will also be calculated to summarise baseline characteristics and outcomes [24,25].

Parameters compared

The parameters that will be compared and evaluated include wound size, depth, necrotic tissue type, granulation tissue formation, exudate amount and type, and epithelialisation, as scored by the BJWAS. Repeated assessment of these parameters over time will enable the establishment of the healing trajectory and the efficacy of the competing treatments. The total score from the BJWAS will be the significant metric used to compare overall wound healing between the two groups.

Level of significance: The significance level for all statistical tests will be set at $p<0.05$. This threshold indicates that any p-value below 0.05 will be considered statistically significant, providing a 95% confidence level in the results. This standard ensures that the findings are robust and reliable, with a minimal chance of Type I errors (false positives) and strong support for the validity of the study's conclusions.

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PARTICULARS OF CONTRIBUTORS:
1. Postgraduate Scholar, Department of Shalyatantra, Mahatma Gandhi Ayurved College and Hospital, DMIHER (Deemed to be University), Salod, Wardha, Jalagaon, Jamod, Maharashtra, India.
2. Professor and Head, Department of Shalyatantra, Mahatma Gandhi Ayurved College and Hospital, DMIHER (Deemed to be University), Salod, Wardha, Jalagaon, Jamod, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Shubham Bhagwan Patil,
Jalagaon, Jamod, Maharashtra, India.
E-mail: iamdrshubh7@gmail.com

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