

Study Protocol



Efficacy of *Dantaraksha* toothpaste in comparison to Pediflor Kidz toothpaste in prevention of *Krimidanta*, early childhood caries - A double blind randomized controlled clinical trial.

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ABSTRACT:

Introduction: *Krimidanta* (Dental caries) is most prevalent among *Dantaroga* (dental diseases). It manifests with tooth cavitation, loosening, oozing, swelling, pain, and tenderness. *Krimidanta* is similar to dental caries. In India, 80% prevalence of tooth decay noted in children. Dental caries continues to be a major concern despite improved public awareness on oral hygiene, various new teeth cleaning agents and regular minerals and vitamin supplementation. Fluoride has been acting as "wonder drug" in the prevention of dental caries and is widely used in toothpastes and mouthwashes. However, the use of fluoride toothpaste in children causes side effects. In response to these concerns, recent research has explored the use of herbal alternatives—such as herbal toothpastes, powders, and gargles for the prevention and treatment of dental disorders. However, only one study till date has shown similar effectiveness in children. This study will explore medicinal plants such as *Arka*, *Arjuna*, *Neem*, *Amalaki*, *Haritaki*, *Vibhitaki*, *Karanja*, *Lavanga*, and *Nyagrodha*, traditionally recommended for Danta Dhavana (tooth brushing) under *Dantaraksha Vidhi* (oral hygiene practices). Additionally, natural ingredients like *Sphatika* (alum), *Khatika* (chalk), *Madhu* (honey), and *Saindhava* (rock salt) will be included in a non-fluoride toothpaste formulation for evaluating their role in the prevention and management of *Krimidanta*. Here we are going to assess the dental caries by the DMFS Index grading. **Materials and Methods:** This is a prospective, closed-label, randomized controlled clinical trial of total of 50 participants diagnosed with dental caries. **Trial group:** Participants in the trial group will receive *Dantaraksha toothpaste*: The treatment will be administered for 45 days. **Control Group:** Participants in the control group will receive Pediflor kids toothpaste in same way. **Conclusion:** The study's findings may potentially demonstrate that the Ayurvedic intervention of *Dantaraksha toothpaste* is as effective as Pediflor kidz *toothpaste* in managing *Krimidanta Early childhood caries*.

KEYWORDS: *Krimidanta*, early childhood caries, *Dantaraksha toothpaste*, DMFS Index.

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1. INTRODUCTION

Krimidanta, is one of *Dantaroga* described in *Ayurveda*, has symptoms such as cavitation in teeth, loosening, oozing, swelling, pain, and tenderness. [1] In its acute form, it can hamper chewing and speech. *Krimidanta* is similar with dental caries, is the most prevalent oral health issue worldwide. [2] In India, caries prevalence rate is 80% among children suffer from caries. [3] Caries is mostly caused, by the acid-mediated erosion of tooth enamel, triggered by bacterial fermentation of dietary sugars. [4] Fluoride is widely accepted as an effective agent in the prevention of dental caries, and its incorporation in toothpaste and mouthwash has been extensively promoted. [5] However, the use of fluoride toothpaste in children has raised problems like risk of fluorosis, as young children are more likely to swallow toothpaste. [6] Fluoride toothpaste can contribute up to 80% of the total daily fluoride intake. [7] Due to these, there has been increasing interest in herbal alternatives such as tooth powders, gargles, and toothpaste for managing dental issues like plaque and gingivitis. [8] While studies on adults have showed positive results, research in paediatric populations remains very rare. [9] A study evaluating UDM *churna* found it effective against dental caries in children when compared to fluoride. [12] Furthermore, only one study has demonstrated that herbal toothpaste can effectively treat children's plaque and gingivitis on par with fluoride toothpaste. In adults, Sudanta toothpaste, herbal formulation, performed similarly to toothpastes containing fluoride. [13] Comprehensive research on children's use of herbal toothpaste for caries, is however, lacking. [14][15]

2. OBJECTIVES:

Primary Objective:

- To evaluate the efficacy of *Dantaraksha* toothpaste in relieving the clinical features of *Krimidanta*, Early Childhood caries based on the DMF Index.

Secondary Objective:

- To compare efficacy of *Dantaraksha* toothpaste with Pediflor Kidz toothpaste in the prevention of *Krimidanta* based upon Dental Caries Severity Index for Primary Teeth and oral hygiene based upon - simplified oral hygiene index
- To document the risks associated with caries

Trial design

It is prospective closed label double blind randomized controlled clinical trial, equivalent trial with two parallel groups and primary end point of for a period of 45 days with randomized allocation.

Study setting

Both of the groups will be treated for the Dental caries from the same center, SDM Institute of Ayurveda and Hospital, Bangalore.

Study duration:

Total duration of clinical study is 45 days

Eligibility criteria

ICD-10 code K02.9

Patients must provide written informed consent before undergoing any study procedures.

Inclusion criteria:

1. Children between the ages of 3 and 6 years, regardless of gender, who show signs of *Krimidanta* (dental caries) along with at least two

of the symptoms listed in the diagnostic criteria, will be eligible to take part in the study.

2. Only those children whose parents are willing to let them participate and are ready to sign the consent or assent form will be included.

Exclusion criteria:

1. Children who have severe gum disease.
2. Children with dental braces or other orthodontic devices.
3. Children who have taken antibiotics for dental issues within the past month.
4. Children who have been using mouthwash regularly in the past three months.
5. Children with other existing oral health conditions.
6. Children who are allergic to toothpaste or any of its ingredients.

Interventions: Treatment of the trial group will include oral administration of *Dantaraksha* toothpaste for a period of 45 days. Treatment of the control group will include oral administration of Pediflor kidz toothpaste for a period of 45 days. Table 1 gives comprehensive idea of study plan.

Methodology

Here we are giving a *Dantaraksha* toothpaste for a trial group for 45 days of span and will educate the parents how to brush a tooth by a rolling method technique whereas, for control group we are giving pediflor kids toothpaste for 45 days along with the same technique of brushing will be explained.

Table 1 gives comprehensive plan of study.

Concomitant care

Details of concurrent illness / medications consumed by participants registered under the trial will be recorded in case report form. Registered patients will

be instructed to avoid the use of any other drugs on their own for any ailment and will be clearly instructed to consult the treating Investigating physician for any symptom or complaint, or if they feel anything unusual. The Investigating physician will record any medication(s) he / she may prescribe to alleviate their concurrent ailments.

Table 1: Study Schedule

Study event	Baseline	Day 45	Day 60
Baseline assessment	✓		
Decayed Missing and Filled Surfaces (DMFS) Index			
Informed consent	✓		
Recruitment			
Demographic profile	✓		
Intervention (45 days)	✓	✓	✓
Follow-up		✓	✓
Assessment by clinical evaluation	✓	✓	✓
Decayed Missing and Filled Surfaces (DMFS) Index	✓	✓	✓
Drug compliance	✓	✓	✓
Rescue medication (If required)	✓	✓	✓
Assessment of adverse events		✓	✓

Discontinuation/modification criteria: To alleviate any emergency, the use of rescue medication is permitted as per the wisdom/discretion of the Principal Investigator. However, the same will be documented in appropriate Column in the Case Record Form.

Adherence monitoring strategy: Parents are advised to keep track of symptoms and report via electronic media.

3. OUTCOMES

Primary outcome measure:

1. Reduction in clinical features of *Krimidanta* based on graded clinical parameters and DMFS index at the end of 6 weeks and 8 weeks

Secondary outcome measures:

1. To compare the improvements in clinical features of *Krimidanta*, Early childhood caries between trial and control group in children based on oral hygiene index and DMF Index.
2. Identification of risk factors associated with *Krimidanta* (ECC) at start point

Sample size:

The sample size is determined using a standard formula. Sample size has been calculated based upon the Standard deviation of Previous Clinical study.

$$n = 2 (SD)^2 \times (Zb^2 + Z1a^2) / d^2$$
$$= 2 (15.4)^2 \times (0.84 + 1.96)^2 / (10)^2 = 3718.6688 / 100 = 37.18$$

n= sample size

- $Z\alpha=1.96$ for 95% early childhood caries
- SD= Assumed Standard deviation (obtained from previous research) as

SD = from previous study [11]

Looking into the feasibility and time constraints, Sample size for current study will be 25

Unblinding – Not applicable

Retention plan – All the participants will be committed through electronic media by creating groups during therapy follow up on 15th day, post follow up therapy on 60th day.

Recruitment:

Study group: 25 children under the age group of 3-6 years visiting Kaumarbhritya and Dental OPD of SDM Bengaluru with features of *Krimidanta* will be taken for the study

Control group: 25 children under the age group of 3-6 years visiting Kaumarbhritya and Dental OPD of SDM Bengaluru with features of *Krimidanta* will be taken for the study

Allocation and concealment: Random allocation using computer generated random tickets which will be kept labelled in an opaque sealed cover, to be opened in front of guide while starting the intervention.

Methods

Current research will be a closed-label, interventional, prospective randomized controlled clinical trial.

Data collection method:

Data will be collected using a specially designed Case Report Form (CRF) and assessment tools used would be the DMFS Index.

Data management

The collected data will be recorded in a specially designed Case Report Form (CRF) by the researcher and later transferred to MS Excel and IBM SPSS Version 26 for analysis.

Statistical methods:

For statistical analysis, the data will be obtained using Case Report form (CRF) designed encompassing all aspects for the study and will be compiled on to a MS office excel sheet. Data will be tabulated and analysis will be done using SPSS (Statistical package for social sciences) version 26 for the following statistical test.

Descriptive Statistics:

Demographic data and other relevant descriptive information will be analyzed with descriptive statistics expressing in Frequency (f), Percentage (%) and Range. Nominal and Ordinal data will be expressed in Median and Percentages. Continuous data and will be expressed in mean, standard deviation.

Inferential Statistics:

To infer the clinical study and to draw conclusions Parametric and Non-Parametric tests will be applied accordingly.

Level of significance: $P < 0.05$

Non-parametric test: For subjective data, Wilcoxon signed ranked test will be employed to assess before and after treatment differences within the group. Mann-Whitney U test will be done between the trial and control group. For multiple comparison of more than 2 sets within same group – Friedman’s test for non-parametric data would be used.

Parametric test: For objective data, Unpaired t test will be assessed between the group and Paired t test will be assessed within the group before and after treatment. Categorical data would be assessed with Chi square test. Effect size is calculated by Cohen’s D Formula.

Data monitoring

The researcher and guide will oversee data monitoring, ensuring adherence to the intervention protocol, tracking adverse effects, and managing participant enrolment.

Auditing: Since it is a small trial external audit is not applicable. Self-funded

Interim analysis & stopping rules – No plan to do interim analysis it’s a short duration PG research work.

Safety measures and managing adverse effects

While the proposed protocol is not expected to cause serious side effects, the monitoring team will document any unexpected occurrences during or after the intervention and promptly inform relevant specialists. The parent will record any such events and notify the lead investigator. Before the study begins, parents will be asked about any food allergies. Any significant adverse effects will be documented and included in the trial’s final report.

Protocol amendments – During the course of research if any factors found to affect the safety and scientific quality of research the same will be, informed to Institutional ethical committee within 24 hours and if required amendments are done taking case to ensure that research remains ethical valid and in compliance with guidelines.

Ethical issues and informed consent

On May 20, 2024, the Institutional Ethics Committee of Sri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital (SDMIAH) granted the trial ethical approval (SDMIAH/IEC/56/2024). On 05/03/2025, the trial has been registered prospectively with the Clinical Trial Registry India (CTRI) CTRI/2025/03/099082 The researcher will adhere to the Helsinki statement, to maintain ethical principles. The trial participants will sign a written informed consent before enrolment. The respondent’s participation will be voluntary, and they will have the ability to leave at any point during the trial. Withdrawal from the trial will not make any effect on their treatment process. The completed trial dataset will be made available to the primary investigator, data auditors, and authors when the

procedure has been made anonymous. The investigators are independent individuals who evaluate the patients and record their findings in hard copies; they are under contract not to disclose or have access to the final data. If there are any unfavourable consequences, there will be post-trial treatment.

Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable - not applicable

Declaration of interests - no competing interests

Study status

Open for recruitment

Dissemination

After the end of the trial, a research paper will be submitted to an indexed journal for publication of the original research. A structured awareness program will also be organized if the study results are found to be effective. The trial results will be published as open access to ensure maximum visibility of the original research.

4. DISCUSSION

Early childhood dental caries is one of the most concerning issues in childhood. Fluoride containing toothpaste though efficacious cannot be used longer for time owing to the risk of permanent damage to enamel. Hence, there is rising interest towards natural alternatives as a toothpaste or denitrifies. The current study aims at exploring efficacy of indigenous toothpaste prepared from twigs described for *dantaraksha* in *Ayurveda*. If proven effective it can be promoted in large scale at primary care level for prevention of early childhood caries.

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