# Expertly Navigating Oral Healthcare Research

## Evaluate the Safety & Efficacy of Test Toothpaste Formulation in Dental Care

### Case Study

Cliantha Research, a full-service Clinical Research Organization (CRO), is a leading provider of clinical research services. With >72 years of experience in consumer research, Cliantha expertly navigates oral healthcare research with reliable claim results.

Cliantha has worked with many multinational companies for efficacy and safety studies of oral care products and has contributed through research in developing various currently available global brands.

By leveraging our in-depth knowledge base and research efficiencies, Cliantha has once again completed safety and efficacy study of tooth paste in dental care at India site.

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| Type of Studies | Evaluate the Safety and Efficacy Test Toothpaste Formulation in Dental Care with Limited Reference Negative and Positive Control Groups. |
| Summary: | The objective of the study is to evaluate the efficacy and safety of the test toothpaste formulas in Dental Care among test products with limited reference negative and positive control groups. The control groups were limited to visit 2 when the germ protection and malodor parameters was evaluated. Negative control group was only rinsing the oral cavity with water and the positive control group was administered with marketed toothpaste. The control groups had served as reference groups for methodology validation. |
| Objectives | <u>Primary</u>:<br>1. Germ protection.<br>2. Oral malodor control<br><u>Secondary</u>:<br>1. Plaque reduction.<br>2. Reduction in gingivitis (inflammation of gums).<br>3. Evaluation of salivary Alkaline Phosphatase (ALP)/ Acid Phosphatase (ACP) as early biochemical markers of periodontitis.<br>4. Assessment of whiteness of the teeth and reduction in extrinsic stain using stain index by dentist.<br>5. Evaluation of relief in dentinal sensitivity by thermal testing using hot |

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| | thermoplastic filling material and cold spray for absent, mild, moderate or severe response.<br>6. Evaluation of superficial dental caries.<br>7. Evaluation of protection against the effect of acid erosion of tooth enamel.<br>8. Assessment of adverse event in oral cavity of test product (if any), assessed by Dentist along with self-reporting by subjects.<br>9. Subjects' perception on taste, long lasting effect for freshness, cooling sensation and mouth feel. |
| Study Population: | Healthy subjects with T-VSC (total volatile Sulphur compounds) of > 160ppb (parts per billion) and subjects with mild, moderate and severe plaque with plaque index 2-4. |
| Subject Recruitment Completion | Within 21 Days |
| Highlights | **Chose an astute Project team with good Oral \| Dental care study experience**<br>• Ensures the selection of subjects through in-house volunteers' database, field work, walk-ins.<br>• Subject retention was maintained due to team's dedication, skill, know-how, and training.<br>• Deployment of in-house inter and intra observer variability for Plaque Index, Extrinsic Stain Index, Gingivitis Index and Shade of Teeth's within and between panel of dentists to established observer variability and good observer reproducibility within all observers before study conduct.<br>• Dedicated In-house Microbiology lab for germ protection claim.<br>• Meeting Project Deadlines<br>• End-to-end service from protocol development, CTRI \| Clinical Trial. Gov registration, statistics to clinical study report writing and manuscript writing. |

**Contact Cliantha for more information about how we can make your oral healthcare research studies successful.**

info@cliantha.com or visit www.cliantha.com