

Expertly Navigating Oral Healthcare Research

Effect of Dark Chocolate on Dental Caries 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 completed a Safety and Efficacy Study of Dark Chocolate on Incidence of Dental Caries at our clinical India site.

Study Title:	Safety and Efficacy Study of Dark Chocolate on Incidence of Dental Caries
Introduction	There are many factors that contribute to the development of dental caries, of which diet plays an important role. Sucrose or commonly called table sugar has always been billed as “arch criminal” of dental caries. Chocolate, being a source of the sugars, containing both sucrose, has been implicated as a cause of dental caries (Curzon, 1999). The relative cariogenicity of chocolates is dependent on their composition, texture, solubility, retentiveness and ability to stimulate salivary flow. The composition of the chocolates has profound impact on its cariogenic potential (Verakaki and Duggal, 2003). Chocolates usually contain cocoa in varying concentrations and it has been suggested that increasing concentrations of cocoa in chocolates prove to be less cariogenic (Morrissey et al., 1994). Considering the wide use of chocolates by both adults and children and the incidence of dental caries, it was intended to conduct an open label study on healthy human subjects with objective to evaluate the safety and efficacy of Sugar Free Dark chocolates containing maltitol on salivary pH through salivary pH measurement and formation of <i>S. mutans</i> .
About Study	This dental study on Dark Chocolate was to substantiate claim of “No Tooth Decay” by using USFDA 21 CFR Part 101 for Food labelling, Health Claims, Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries.

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Objective	The objective of the study was to evaluate the safety & effect of chocolate formulation containing Maltitol on factors associated with Dental Caries using salivary pH measurement and Saliva microbial testing for <i>S. Mutans</i> .
Study Summary:	This was an open label, non-randomized dental study with objective to evaluate the safety and efficacy of test product containing Maltitol on salivary pH through salivary pH measurement and formation of <i>S. mutans</i> by Saliva microbial testing for <i>S. mutans</i> which are associated factor for Dental caries. To assess safety of the test product by the Dentist along with self-reported by subjects and subject's participating parent/ legal guardian/caregiver in case of child subject.
End Points	<u>Primary:</u> Change in salivary pH using Digital pH meter after consumption of test product from baseline to 0 hours, 1 Hours, 2 Hours and 4 Hours after test product consumption on Day 1. <u>Secondary:</u> Effect of Test product on <i>S. mutans</i> formation by saliva sample testing with respect to change from baseline to 0 Hours) and 4 Hours on Day 1.
Site(s)	India
Study Population	Mixed – Healthy Kids, Males and Females.
Number of Subjects	09 females and 06 males(age ranged from 2 to 35 years)

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

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