The effectiveness of a newly developed Zendium dentifrice in the treatment of gingivitis.

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Aim: The aim of the present study was to evaluate the effect of a colostrum & zinc-containing Zendium dentifrice on gingivitis in an 8-week clinical trial.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON29921

Source
ToetsingOnline

Brief title
Zendium toothpaste

Condition

- Other condition

Synonym
inflammation of the gingiva

Health condition

gingivitis

Research involving
Human

Sponsors and support

Primary sponsor: Sara Lee Household & Bodycare, R & D Oral Care
Source(s) of monetary or material Support: Sara Lee Body Care Research

Intervention

Keyword: gingivitis, manual toothbrush, plaque, zinc

Outcome measures

Primary outcome

Endpoint: by standardized measurements and score procedures determine the

effect of the oral hygiene procedure on levels of plaque and gingival abrasion

over the evaluation period.

Secondary outcome

nvt

Study description

Background summary

Background: Control of plaque on the tooth surfaces is the most important method of controlling dental disease. A manual toothbrush is the most popular mechanical method of plaque control. In spite of the activity in improving toothbrush type and design, most people still remove only approximately 50% of the plaque present when they brush their teeth (Jepsen 1998). The development of a dentifrice that would allow the average person to control plaque and gingivitis would be desirable.

Study objective

Aim: The aim of the present study was to evaluate the effect of a colostrum & zinc-containing Zendium dentifrice on gingivitis in an 8-week clinical trial.

Study design

Material and methods: The study is designed to evaluate the effect of a colostrum & zinc-containing Zendium dentifrice on gingivitis in an 8-week

clinical trial. 180 subjects (non-dental) will be selected on the basis of having moderate gingival inflammation. At baseline, plaque (Quigley & Hein), bleeding upon marginal probing (BOMP), and gingival abrasion (GA) will be assessed. Subjects will be randomly divided among 3 groups; group 1 will brush with a Zendium toothpaste with enzymes, colostrum, a low concentration zinc and with lysozyme, group 2 will brush with a control dentifrice with fluoride and group 3 will brush with a Zendium toothpaste with enzymes, colostrum, a low concentration zinc and without lysosym. All groups will brush with a normal manual toothbrush. After 4-weeks and after 8-weeks the clinical indices will be assessed again. At each assessment the participants will receive a new manual toothbrush.

Intervention

Intervention: Improvement of gingival health by removing plaque and avoiding gingival abrasion with the manual toothbrush and zinc containing toothpaste.

Study burden and risks

Risk for subjects: none.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

At least 5 evaluable teeth in each quadrant

Exclusion criteria

No partial dentures, orthodontics banding or wires
No oral lesions or periodontal pockets >5mm

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	19-09-2006
Enrollment:	180
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL13630.018.06