ISRCTN24643598 https://doi.org/10.1186/ISRCTN24643598

Clinical trial of a toothpaste containing enzyme (dextranase) on the control of dental plaque

Submission date
01/08/2025

Recruitment status
No longer recruiting

Registration date
11/08/2025

Overall study status
Completed

Last Edited
11/08/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
To evaluate the efficacy of a toothpaste containing dextranase, an enzyme that degrades α-1,6 glycosidic bonds in glucans, both alone and in combination with isopropyl methylphenol (IPMP), a non-ionic antimicrobial agent, for inhibiting dental plaque.

Who can participate?
Adults aged 19–70 years in generally good health, with no major systemic illness or oral injuries, who have at least 20 natural teeth (including 4 molars, excluding third molars), are not currently in other trials, and have a plaque index (PI) score of 2 or higher. Participants must also be able to complete the trial and give informed consent.

What does the study involve?
Participants were randomly assigned to one of three toothpaste groups and instructed to brush their teeth twice daily for 8 weeks using only the assigned products. Their dental plaque was assessed at baseline and after 2, 4, and 8 weeks using a standardized index. No other oral hygiene products were allowed. Oral examinations, plaque staining, and PI scoring were conducted by trained professionals.

What are the possible benefits and risks of participating?
Oral plaque inhibition

Where is the study run from?
The study was conducted at the Chongqing Medical University (China)

When is the study starting and how long is it expected to run for?
April 2024 to October 2024

Who is funding the study?
Lion Corporation, Japan

Who is the main contact?
Dr Zhou Zhi, zhouzhi_050918@hotmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Zhi Zhou

ORCID ID
https://orcid.org/0000-0001-7402-0037

Contact details
No. 426, Songshi North Road, Yubei District
Chongqing
China
401147
+86-23-88860111
zhouzhi_050918@hotmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Clinical trial of a toothpaste containing enzyme (dextranase) on the control of dental plaque

Study objectives
Both test toothpastes—with dextranase alone or in combination with IPMP—significantly reduce the plaque index compared with the control. Additionally, superior plaque inhibition is observed for the formulation combining a higher dose of dextranase with IPMP.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/05/2024, The Ethics Committee of the Stomatological Hospital of Chongqing Medical University (No. 426, Songshi North Road, Yubei District, Chongqing, 401147, China; +86-23-88602305; kqyyirb@163.com), ref: No. 2024 Ethics Review 084

Study design

Randomized double-blind parallel-controlled clinical trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Plaque control in healthy individuals

Interventions
The participants were instructed to brush their teeth twice a day, once in the morning and once at night, for 2 min each time using the provided toothpaste and toothbrush. The amount of toothpaste used for each brushing was enough to cover the entire length of the brush head.

Group 1: Toothpaste containing dextranase alone, brushing twice daily (morning and night) for 2 minutes each time.
Group 2: Toothpaste containing dextranase + isopropyl methylphenol (IPMP), brushing twice daily (morning and night) for 2 minutes each time.
Group 3: Control toothpaste without dextranase or IPMP, brushing twice daily (morning and night) for 2 minutes each time.

All participants were instructed to refrain from using any other oral care products (toothpaste, toothbrushes, mouthwashes, dental floss, toothpicks) during the study.
Follow-up assessments: Baseline, 2 weeks, 4 weeks, and 8 weeks.

Randomisation: Randomisation was performed using a computer-generated randomisation list, stratified by baseline plaque index (PI), age, and gender to ensure balanced allocation between groups.

Intervention Type
Other

Primary outcome(s)
Plaque index measured using the Turesky modification of the Quigley–Hein index at baseline, 2 weeks, 4 weeks, and 8 weeks, assessed by trained dental examiners using plaque disclosing agents.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
02/10/2024

Eligibility

Key inclusion criteria
1. They were in good overall health, had no significant systemic diseases, had no injuries inside or outside the oral cavity, and had at least 20 testable teeth. Excluding the third molars, they

must have at least four molars
2. They were between the ages of 19 and 70 years
3. They were not participating in other similar trials simultaneously
4. They could complete the clinical trial as required if they signed the informed consent
5. Based on the claimed efficacy of the product and clinical trial design, participants must have an appropriate level of plaque, with a baseline PI score of ≥2

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
19 years

Upper age limit
70 years

Sex
All

Total final enrolment
186

Key exclusion criteria
1. They had orthodontic appliances, implants, locally movable dentures, or orthodontic retainers in their oral cavity
2. They had severe diseases such as oral soft and hard tissue tumors
3. They had two or more teeth that needed immediate treatment or had mucosal lesions
4. They were participating in other clinical trials
5. They had a history of hypersensitivity to the test toothpaste ingredients
6. They had used antibiotics within the last month
7. They planned to receive treatment at a dental clinic during the test period
8. They were pregnant or breastfeeding or planned to become pregnant during the test period
9. They were smokers, including electronic cigarettes, or had a recent history of smoking

Date of first enrolment
02/06/2024

Date of final enrolment
20/06/2024

Locations

Countries of recruitment
China

Study participating centre
Stomatological Hospital of Chongqing Medical University
Chongqing
China
401147

Sponsor information

Organisation
Lion Corporation (Japan)

ROR
https://ror.org/01bt8n520

Funder(s)

Funder type
Industry

Funder Name
Lion Corporation

Alternative Name(s)
Lion, Lion Corp, Lion Corporation Japan,

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Japan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr. Zhi Zhou (zhouzhi_050918@hotmail.com)

IPD sharing plan summary

Available on request