

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

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<b>Registration date</b> 11/08/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/08/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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  $\alpha$ -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

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

**Secondary study design**

Randomised parallel trial

**Study setting(s)**

University/medical school/dental school

**Study type(s)**

Efficacy

**Participant information sheet****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 measure**

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.

**Secondary outcome measures**

There are no secondary outcome measures

**Overall study start date**

02/04/2024

**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  $\geq 2$

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Lower age limit**

19 Years

**Upper age limit**

70 Years

**Sex**

Both

**Target number of participants**

180

**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)

**Sponsor details**

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**Sponsor type**

Industry

**Website**

<http://www.lion.co.jp/en/>

**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**

**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

**Intention to publish date****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