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Toothpastes containing potassium nitrate alone versus potassium nitrate combined with aluminum lactate in reducing dentin hypersensitivity

Submission date
12/12/2025

Recruitment status
No longer recruiting

Registration date
18/12/2025

Overall study status
Completed

Last Edited
18/12/2025

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
This study aims to evaluate whether two types of desensitizing toothpastes can reduce dentin hypersensitivity, a condition that causes short, sharp pain when exposed dentin reacts to stimuli such as touch or air. The trial compares a toothpaste containing 5% potassium nitrate alone with another containing 5% potassium nitrate combined with 2.18% aluminum lactate, against a placebo toothpaste.

Who can participate?
Adults aged 18 to 65 years in good general health who have at least one tooth with cervical or gingival recession and dentin hypersensitivity confirmed by tactile or air stimulation tests. Female participants must not be pregnant or breastfeeding.

What does the study involve?
Participants are randomly assigned to one of three groups: two test groups and one placebo group. They will use the assigned toothpaste twice daily for eight weeks. Sensitivity is assessed at baseline, immediately after the first brushing, and at 2, 4 weeks plus 24 hours, and 8 weeks using standardized tests for tactile and air stimulation.

What are the possible benefits and risks of participating?
Participants may experience relief from dentin hypersensitivity, improving comfort during eating, drinking, and oral hygiene. There are no known medical risks, as the intervention involves standard toothpaste use and is non-invasive.

Where is the study run from?
The study is conducted at the Stomatological Hospital of Chongqing Medical University, China.

When is the study starting and how long is it expected to run for?
June 2022 to December 2022.

Who is funding the study?
The Lion Corporation, Japan.

Who is the main contact?
Dr Zhi Zhou, Stomatological Hospital of Chongqing Medical University, China, zhouzhi_050918@hotmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Toothpastes containing potassium nitrate alone versus potassium nitrate combined with aluminum lactate in reducing dentin hypersensitivity: a randomized controlled trial

Study objectives
This study is designed to assess and compare the clinical efficacy of two desensitizing toothpastes—one formulated with 5% potassium nitrate and the other with 5% potassium nitrate plus 2.18% aluminum lactate—in alleviating dentin hypersensitivity.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/05/2022, Ethics Committee of the Affiliated Stomatological Hospital of Chongqing Medical University (No. 426, Songshi North Road, Yubei District, Chongqing, 401147, China; +86-023-88602305; 500119@hospital.cqmu.edu.cn), ref: 2022 Ethics Review (042)

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Device feasibility

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Dentin hypersensitivity in adults with at least one anterior tooth exhibiting cervical or gingival recession and sensitivity to tactile or air stimulation.

Interventions
This is a single-centre, randomized, double-blind, placebo-controlled, parallel-group clinical trial conducted to evaluate the immediate and sustained effects of desensitizing toothpastes on dentin hypersensitivity. The intervention involves the use of two test toothpastes and one placebo toothpaste. The first test group uses a toothpaste containing 5% potassium nitrate, while the second test group uses a toothpaste containing 5% potassium nitrate combined with 2.18% aluminum lactate. The placebo group uses a toothpaste with the same base formulation but without active desensitizing ingredients. All products are identical in appearance, flavor, and packaging to ensure blinding. Participants are instructed to brush their teeth twice daily for 2 minutes using the assigned toothpaste for 8 weeks. Assessments of dentin sensitivity are performed at baseline, immediately after brushing, and at 2 weeks, 4 weeks, 4 weeks plus 24 hours, and 8 weeks.

Method of randomisation:
The randomisation method used was stratified randomisation (by baseline sensitivity) with parallel assignment across three groups.
Stratification factor: Participants were first stratified by their maximum baseline Schiff sensitivity score for the two selected test teeth to ensure balance in baseline sensitivity severity across groups.
Randomisation within strata: After stratification, participants were randomly assigned to three parallel groups within each stratum.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Toothpaste (5% potassium nitrate), toothpaste (5% potassium nitrate plus 2.18% aluminum lactate)

Primary outcome(s)
1. Dentin hypersensitivity measured using the Dentin Sensitivity Index (DSI) for tactile stimulation (Yeaple probe, grams) and air stimulation (Schiff score) at baseline, immediately after brushing, and at 2, 4, and 8 weeks of toothpaste use

Key secondary outcome(s))
1. The immediate desensitizing effect after a single brushing measured using the Dentin Sensitivity Index (DSI) for tactile and air stimulation at the initial visit

2. The sustained desensitizing effect measured using the Dentin Sensitivity Index (DSI) for tactile and air stimulation at 24 hours, following 4 weeks of use

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Adults aged 18–65 years in good general health
2. At least one dentin-sensitive tooth with cervical or gingival recession, sensitive to tactile stimulation (10–50 g) or air stimulus (Schiff score ≥ 2)
3. Able to attend all scheduled examinations during the 8-week study period
4. Willing to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Severe systemic or chronic diseases
2. Advanced periodontal disease or periodontal treatment within the past year
3.Teeth with extensive restorations, suspected chronic pulpitis, caries, or enamel cracks
4. Current use of desensitizing toothpaste or participation in other clinical trials within the past 3 months
5. History of allergy to oral care products or ingredients

Date of first enrolment
01/06/2022

Date of final enrolment
01/07/2022

Locations

Countries of recruitment
China

Study participating centre
West China School/Hospital of stomatology, Sichuan University
-
-
China
610041

Sponsor information

Organisation
Lion Corporation (Japan)

ROR
https://ror.org/01bt8n520

Funder(s)

Funder type
Not defined

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 and/or analyzed during the current study will be available upon reasonable request to the corresponding author (Dr. Zhi Zhou, zhouzhi_050918@hotmail.com). Data will be anonymized and shared only with qualified researchers for academic purposes. Participant consent was obtained, and ethical approval was granted for data use in this context.

IPD sharing plan summary
Available on request