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Study on the whitening and sensitive relief effects of LESENING Teeth Strips

Submission date
27/02/2025

Recruitment status
No longer recruiting

Registration date
07/03/2025

Overall study status
Completed

Last Edited
04/03/2025

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
At-home tooth bleaching using low concentration peroxide has become a widely popular over-the-counter dental treatment. However, it is known to induce temporary dentin hypersensitivity following the whitening with peroxide. Potassium nitrate has been proven to effectively alleviate dentin hypersensitivity. The study objective was to evaluate the tooth whitening efficacy and tooth sensitivity of a novel whitening strips with 3% hydrogen peroxide and 1.5% potassium nitrate.

Who can participate?
Healthy participants, aged 18 to 60 years old, who were willing to whiten their teeth

What does the study involve?
Participants were randomly assigned into two groups: an experimental group using LESENING Whitening Strips with 3% hydrogen peroxide and 1.5% potassium nitrate, and the control group using Crest 3D Whitestrips only with 3% hydrogen peroxide. Tooth sensitivity was evaluated using scoring methods and tooth color and color change were assessed using laboratory methods, with assessments made at baseline and after 7, 14, 21, and 28 days of use.

What are the possible benefits and risks of participating?
Participants could receive tooth strips for free to make their teeth white and acquire dental aesthetics. During the trial process, experienced clinical doctors would provide diagnosis and treatment for all participants, closely monitoring changes in their oral hygiene status after enrollment. Due to the randomization and blinding, participants might undergo side effects of tooth-whitening such as dentin hypersensitivity or gingival ulcer. Clinicians would provide immediate safe treatments when these conditions happened.

Where is the study run from?
Affiliated Stomatological Hospital of Chongqing Medical University, China

When is the study starting and how long is it expected to run for?
May 2024 to August 2024

Who is funding the study?
1. Supported by Dencare Oral Care Co. Ltd., China
2. The Northern Department of Endodontics, Stomatological Hospital of Chongqing Medical University, China

Who is the main contact?
Prof Deqin Yang, 500246@hospital.cqmu.edu.cn

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Study on the whitening and sensitive relief effects of LESENING Teeth Strips containing 3% hydrogen peroxide and 1.5% potassium nitrate

Study objectives
The null hypothesis was that the LESENING Whitening Strips would have no effect on tooth color change and that there would be no difference in sensitivity between the LESENING and Crest strips.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 31/05/2024, The Ethics Committee at the Affiliated Stomatology Hospital of Chongqing Medical University (No. 426, Songshi North Road, Yubei District, Chongqing, 400000, China; +86 23 8860 2305; CYKQ_EC@163.com), ref: 202401

Study design
Single-center interventional randomized double-blind clinical trial

Primary study design
Interventional

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Treatment for tooth discoloration and prevention of tooth hypersensitivity after tooth whitening.

Interventions
The trial was to compare the whitening efficacy and anti-sensitivity effects of LESENING Whitening Strips with that of Crest 3D Whitestrips. Following the initial examination, all participants signed informed consent forms and agreed to attend scheduled follow-up visits. They promised to use the designated non-fluoride toothpaste, not to use other whitening or anti-sensitivity toothpaste and desensitization drugs, and not to receive treatment that affected the color and sensitivity of the teeth during the study period. Participants were randomly assigned into two groups: an experimental group using LESENING Whitening Strips with 3% hydrogen peroxide and 1.5% potassium nitrate, and the control group using Crest 3D Whitestrips only with 3% hydrogen peroxide. The appearance of the two products was identical. Randomization was performed by an independent staff who was not involved in the study. The random number was generated by a random number table. 96 participants were randomly assigned to two groups by SPSS 27.0 software. Once participants were confirmed to be eligible

and had completed baseline assessments, their enrollment numbers were recorded and input into software to determine the group assignment. Every participant's enrollment number and their group was printed and sealed in an envelope.

During the process, participants brushed their teeth twice daily with the given non-fluoride toothpaste and used whitening strips once daily at night before brushing their teeth. First, participants cleaned their hands, tore off the protective cover, and took out the whitening strips. Second, the gel surface of the strip was attached to the buccal surface of teeth 13-23 and gently pressed until it adhered closely. The portion beyond the incisal edge was folded to the palatal surface of the tooth. After 30 minutes, the strips were removed, and teeth were brushed as usual.

The change in tooth color measured by a spectrophotometer (ΔL*, Δa*, Δb*, ΔE*ab, and ΔWID) was the main result. The changes in tooth sensitivity and the safety assessment of any adverse reactions were the secondary results.

Tooth color and sensitivity were measured at five time points: T0 (baseline, before use), T1 (7 days after starting whitening strips), T2 (14 days), T3 (21 days), and T4 (28 days). The maxillary central incisors, lateral incisors, and canines (13, 12, 11, 21, 22, 23; n=6) were measured three times, and the mean value (SDs) was used for data recording. All tooth color and sensitivity assessments during the period were performed by the same clinician. For each measurement, participants rinsed with water, and one clinician measured the color parameters of each tooth position. Sensitivity was assessed by another clinician, who recorded baseline data and provided the test products and instructions.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
LESENING Whitening Strips, Crest 3D Whitestrips

Primary outcome(s)
The following primary outcome measures were assessed at T0 (baseline, before use), T1 (7 days after starting whitening strips), T2 (14 days), T3 (21 days), and T4 (28 days):
1. Tooth color measured using the Vita Easyshade V spectrophotometer:
1.1 CIELAB values (L, a, b)
1.2 ΔL (change in brightness)
1.3 Δa (change in red/green tone)
1.4 Δb (change in yellow/blue tone)
1.5 ΔEab (overall color change)
1.6 ΔWID (Dental Whitening Index)
2. Tooth sensitivity measured using the Schiff score (sensitivity score ranging from 0 to 3)

Key secondary outcome(s))
Subjective evaluation of tooth color was measured using two shade guides, the Vita Classical (VITA Zahnfabrik) and the Vita Bleachedguide 3D-MASTER (VITA Zahnfabrik) before and after whitening

Completion date
23/08/2024

Eligibility

Key inclusion criteria
1. Healthy adults aged 18 to 60
2. Willingness to whiten teeth
3. No tetracycline staining
4. No fluorosis in natural maxillary anterior teeth
5. No external staining from smoking, plaque, or calculus
6. Untreated dentin hypersensitivity
7. Fixed orthodontic devices or removable partial dentures, fillings or crowns
8. Recent use of desensitizing products
9. Involvement in other similar trials

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
96

Key exclusion criteria
1. Severe oral or systemic diseases
2. Allergy to the products
3. Ongoing periodontal disease in teeth 13-23
4. Periodontal treatment within the past year
5. Tooth mobility exceeding grade 1
6. Extensive restorations on the labial surfaces of teeth 13-23, pulpitis, caries, enamel cracks, smoking
7. Pregnancy or breastfeeding

Date of first enrolment
08/06/2024

Date of final enrolment
28/07/2024

Locations

Countries of recruitment
China

Study participating centre
Affiliated Stomatological Hospital of Chongqing Medical University
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Sponsor information

Organisation
Stomatological Hospital of Chongqing Medical University

ROR
https://ror.org/02bnr5073

Organisation
Dencare Oral Care Co. Ltd

Funder(s)

Funder type
Industry

Funder Name
Dencare Oral Care Co. Ltd

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 Prof Deqin Yang, 500246@hospital.cqmu.edu.cn

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes