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Tooth whitening effect of whitening patch with primer

Submission date	Recruitment status	[ ] Prospectively registered
29/07/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/08/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/10/2020	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to evaluate the safety and tooth whitening effect of a tooth whitening patch with primer.

Who can participate?
Adults over 20 years of age with tooth discolouration

What does the study involve?
The effectiveness of whitening is confirmed by attaching a tooth whitening patch with primer for 30 minutes for 10 days. Safety is checked by examining the presence or absence of side effects caused by whitening through questionnaires and oral examinations.

What are the possible benefits and risks of participating?
Possible benefits include effective tooth whitening. Possible risks include gingival (gum) irritation and tooth tingling.

Where is the study run from?
Kyungpook National University (South Korea)

When is the study starting and how long is it expected to run for?
January 2019 to October 2019

Who is funding the study?
LG Household & Health Care Research Park (South Korea)

Who is the main contact?
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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KCT0004625

Study information

Scientific Title
Clinical efficacy of bleaching patch with primer in randomized controlled trial

Acronym
CEPT

Study objectives
To clinically evaluate the efficacy and safety of the primer that contains taurine and self-bleaching patches containing 3.0% hydrogen peroxide.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2019, Kyungpook National University Bioethics Review Committee (Department of preventive Dentistry School of Dentistry, Kyungpook National University 2177 Dalgubeol-daero, Jung-gu, Daegu 41940, Korea; +82 (0)53 2000 5430; knuiars@knu.ac.kr), ref: KNU 2019-0009

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Tooth whitening

Interventions
This is a double-blinded randomized clinical trial that referred to the Consolidated Standards of Reporting Trials (CONSORT) 2010 guideline from design to completion.

Healthy adult applicants interested in tooth whitening are recruited through snowball sampling. The effectiveness of whitening is confirmed by attaching a patch containing 3.0% peroxide and a primer containing a mitigating component for 30 minutes for 10 days. In addition, safety is checked by examining the presence or absence of side effects caused by whitening through self-filling questionnaires and oral examinations.

When applied for at least 30 minutes with a self-whitening patch containing 3.0% peroxide, the efficacy of whitening compared to the placebo-controlled group is confirmed, and the difference between application times of 30 minutes is confirmed.

After applying the taurine-containing primer, a self-administered questionnaire completed asking about the patient's subjective symptoms and an oral examination is carried out for the side effects of whitening to confirm the clinical safety.

Total duration of intervention and follow-up: 18/03/2019 to 26/04/2019.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hydrogen peroxide

Primary outcome measure

Current primary outcome measure as of 09/10/2020:
Tooth color measured using ΔL, Δa, Δb and ΔE with Shade Eye NCC and Vita classical shade guide at baseline, 3, 5, 7 and 10 days

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Previous primary outcome measure:

Tooth color measured using ΔL, Δa, Δb with Shade Eye NCC and Vita classical shade guide at baseline, 3, 5, 7 and 10 days

Secondary outcome measures
Side effects measured using questionnaire, VAS scale and oral examination before patching and after 3, 5, 7 and 10 days

Overall study start date
14/01/2019

Completion date
31/10/2019

Eligibility

Key inclusion criteria
1. Adults over 20 years of age who agree to take the test
2. People with good general health and oral health
3. A person with six maxillary anterior teeth
4. A person with similar level of discoloration of each tooth showing proper tooth discoloration
5. A person who understands the purpose of the test and is able to read and write
6. Who can follow the test procedure and follow the visit schedule
7. Persons who can follow up during the test

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
56

Total final enrolment
55

Key exclusion criteria
1. People with inadequate dentition in the practice of tooth whitening
2. People with resin and porcelain restorations in the anterior region

3. A person who shows signs of inflammation in teeth due to dental caries or dental erosion
4. People with hypersensitivity due to gingivitis and periodontitis
5. People with excessive discolouration due to drugs and congenital anomalies
6. Those who have experienced tooth whitening in the past and have not passed 3 years
7. Women who are pregnant, breastfeeding or have a pregnancy plan during the test
8. Other diseases that may affect the efficacy and safety evaluation of the drug
9. A person who is taking or administering medication
10. People participating in other clinical trials or human attachment tests
11. Anyone who can not communicate or follow instructions
12. Those who do not qualify for the test under the judgment of the other examiners

Date of first enrolment
01/03/2019

Date of final enrolment
29/03/2019

Locations

Countries of recruitment
Korea, South

Study participating centre
Kyungpook National University
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Study participating centre
LG Household & Health Care Research Park
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Sponsor type
University/education

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http://www.knu.ac.kr/wbbs/

ROR
https://ror.org/040c17130

Funder(s)

Funder type
Industry

Funder Name
LG Household & Health Care Research Park

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
08/09/2020

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date