

Tooth whitening effect of whitening patch with primer

Submission date 29/07/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/08/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/10/2020	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Jin-kyoung Kim
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Contact information

Type(s)

Public

Contact name

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Contact details

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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

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

Department of Preventive Dentistry

School of Dentistry

2177, Dalgubeol-daero, Jung-gu

Daegu

Korea, South

41940

Study participating centre

LG Household & Health Care Research Park

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Seoul

Korea, South

-

Study participating centre

Kyungpook National University

Department of Dental Hygiene

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Sponsor information

Organisation

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Sponsor details

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Sponsor type

University/education

Website

<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