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Comparison between three types of at-home dental bleaching for effects and tooth sensitivity

Submission date
02/04/2023

Recruitment status
No longer recruiting

Registration date
12/04/2023

Overall study status
Completed

Last Edited
03/06/2024

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
This study aims to compare the bleaching effects of three different at-home bleaching systems and their longevity after a 6-month follow-up.

Who can participate?
Healthy adults aged 18-35 years old

What does the study involve?
Six anterior upper teeth will be bleached with one of the study's materials (either Opalescence 20% carbamide peroxide, Dazzling white paint-on, or Whitelight system) for each patient. The visual analog scale (VAS) scores and color change values will be assessed to study tooth sensitivity and bleaching longevity.

What are the possible benefits and risks of participating?
Regarding the benefits of participating, participants may get a shiny and whiter smile. All materials used in this trial are safe and should not cause any additional risks. It is crucial for the dentist to minimize the side effects of the treatment and improve the quality of life of his patients.

When is the study starting and how long is it expected to run for?
September 2020 to March 2022

Where is the study run from?
Damascus University (Syria)

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Eenass Krayem, eenasskrayem@gmail.com (Syria)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
3833

Study information

Scientific Title

Evaluation of the tooth sensitivity and efficacy of two systems of over-the-counter teeth whitening products compared with at-home bleaching with carbamide peroxide: A randomized clinical trial

Study objectives
The study will evaluate the tooth sensitivity and efficacy of two over-the-counter dental bleaching products compared with traditional at-home bleaching with 20% carbamide peroxide

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/12/2020, Damascus University (Rector Baramkeh, Damascus, Syria; +966555063806; no email provided), ref: MS3833

Study design
Interventional single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Assessment of tooth sensitivity and the efficacy of dental bleaching products

Interventions
This study is a randomized controlled clinical trial. Participants were divided randomly into three groups by an external person:
Group A: Participants were instructed to apply 20% carbamide peroxide bleaching material using a customized tray (14 days for 4 h each day) (Opalescence PF, Ultradent Products Inc. USA)
Group B: Participants were instructed to use WhiteLight system (an over-the-counter dental bleaching product consisting of prefabricated silicon trays with two carbamide peroxide gel containers and a compact LED unit for activation) (14 days for 30 minutes per day with a light transmitter)
Group C: Participants were instructed to use Dazzling white paint-on (an over-the-counter dental bleaching product containing hydrogen peroxide) (14 days for 10 min twice a day after tooth brushing)
The bleaching materials are applied individually by participants themselves at their homes.

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Opalescence® PF™ (20% carbamide peroxide), Dazzling White (hydrogen peroxide), WhiteLight system (carbamide peroxide)

Primary outcome measure
1. Tooth sensitivity measured using a visual analogue scale (VAS) at baseline, and days 1, 2, 3, 4, 5, 7 and 14 days of bleaching.
2. Color change measured using the Vita easy shade spectrophotometer at baseline, and 7 and 14 days of bleaching, 2 weeks and 6 months after bleaching

Secondary outcome measures
There are no secondary outcomes measures

Overall study start date
01/09/2020

Completion date
10/03/2022

Eligibility

Key inclusion criteria
1. Good general health
2. Adults (aged between 18 and 35 years old)
3. No caries or restoration on the six maxillary anterior teeth
4. Permanent teeth with a shade of A2 or darker on the shade guide (Vitapan Classical, Vita Zahnfabrik)
5. No history of tooth sensitivity
6. Availability for the follow-ups

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
39

Total final enrolment
39

Key exclusion criteria
1. Poor oral hygiene and general health
2. Current or previous use of bleaching agents
3. A history of allergies to tooth bleaching products
4. Orthodontic treatment
5. Parafunctional habits such as bruxism
6. Pregnant or lactating women
7. Advanced periodontal disease or active carious lesions
8. Tetracycline-stained teeth
9. Tooth hypersensitivity or deep cracks in the teeth
10. Smoking

Date of first enrolment
01/02/2021

Date of final enrolment
10/01/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Clinics of the Operative Dentistry Department
Mazzah High Way
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

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

Intention to publish date
10/06/2023

Individual participant data (IPD) sharing plan
The datasets during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			12/04/2023	No	Yes
Protocol file			12/04/2023	No	No
Basic results			14/07/2023	No	No
Dataset			01/08/2023	No	No
Results article		31/05/2024	03/06/2024	Yes	No