

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

<b>Submission date</b> 02/04/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/04/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/06/2024	<b>Condition category</b> Oral Health	<input checked="" type="checkbox"/> 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

### Contact name

Dr Eenass Krayem

### ORCID ID

<https://orcid.org/0000-0003-4328-8836>

### Contact details

Barza

Damascus

Syria

0096311

+963 949347992

eenasskrayem@damascusuniversity.edu.sy

### Type(s)

Public

### Contact name

Dr Eenass Krayem

### Contact details

Barza

Damascus

Syria

0096311

+963 949347992

eenasskrayem@gmail.com

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

### **Study type(s)**

Treatment

### **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(s)**

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

**Key secondary outcome(s)**

There are no secondary outcomes measures

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

Damascus

Syria

0096311

## Sponsor information

**Organisation**

Damascus University

## 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

## 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?
<a href="#">Results article</a>		31/05/2024	03/06/2024	Yes	No
<a href="#">Basic results</a>			14/07/2023	No	No
<a href="#">Dataset</a>			01/08/2023	No	No
<a href="#">Participant information sheet</a>			12/04/2023	No	Yes
<a href="#">Protocol file</a>			12/04/2023	No	No