

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessing the effect of used dental bleaching carbamide peroxide 16% gel on gingival health in 18 to 30 years

Protocol summary

Study aim

evaluation of effect of carbamide peroxide 16% on sulcus bleeding index/Plaque index/Gingival index

Design

30 patients will be selected for clinical trial according to the criteria for inclusion in and exclusion. gingival health in after bleaching and before bleaching compared. without control group study group: consider of gingival health condition before bleaching and reconsider of gingival health condition after bleaching on selfsame patient all patient inclusion in study reconsider after treatment and without blinding and randomised. phase 2-single type of intervention group

Settings and conduct

30 patients referring to the Department of Operative Dentistry, Zahedan Faculty of Dentistry- home special tray for one persone is composing patient's special tray is tested . The tube gel carbamaid proxide 16% is given to each patient with its applying instructions. The time to apply is 4 hours a day in tray until 14 days. The patient refers back after 14 days . In this stage health indices of the gum including bleeding index sulcus and gingival index and plaque index are measured

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 18-30 years Without any anterior treatment People without tooth decay People with no Gingivitis and periodontal diseases People without tooth root spreading People without cervical lesions (Non Caries Cervical Lesions) Non-pregnant and non-lactating women Lack of calculus Non-smokers Non changing the colors caused by fluorosis and tetracycline
Exit criteria: Patients who have not been studied or have not been able to continue treatment.

Intervention groups

bleching with carbamide peroxide 16% gel

Main outcome variables

plaque index sulcus bleeding index gingival index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170210032484N3**

Registration date: **2018-05-11, 1397/02/21**

Registration timing: **retrospective**

Last update: **2018-05-11, 1397/02/21**

Update count: **0**

Registration date

2018-05-11, 1397/02/21

Registrant information

Name

Somayeh Somaye

Name of organization / entity

Dentistary

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-09, 1396/11/20

Expected recruitment end date

2018-04-03, 1397/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of used dental bleaching carbamide peroxide 16% gel on gingival health in 18 to 30 years

Public title

Assessing the effect of used home bleaching on gingival health in 18 to 30 years

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: Non-smokers Women aged 18-30 years With natural anterior teeth with A2, B2, C2, D2 colors and darker (Vitapan Classic Shade) Minimum of 24 teeth Suitable oral hygiene Patient Satisfaction

Exclusion criteria:

People tooth decay People with Gingivitis and periodontal diseases People tooth root spreading People cervical lesions NCCL (Non Caries Cervical Lesions) People who do have Ortho treatment pregnant and lactating women Lack of calculus People bleach treatment history in the past Individuals changing the colors caused by fluorosis and tetracycline any anterior restoration

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

Street address

West Azadegan , Khoramshahr Blvd.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167-43463

Approval date

2018-01-28, 1396/11/08

Ethics committee reference number

IR. ZAUMS. REC.1396.372

Health conditions studied

1

Description of health condition studied

Effect of Carbamide peroxide on Gingival health

ICD-10 code

T49.7

ICD-10 code description

Poisoning by, adverse effect of and underdosing of dental drugs, topically applied

Primary outcomes

1

Description

Gingival index

Timepoint

1to 14 days after start bleaching

Method of measurement

Clinical examination of gingival health index

2

Description

Sulcus bleeding index

Timepoint

1to 14 days after start bleaching

Method of measurement

Probing

3

Description

Plaque index

Timepoint

1to 14 days after start bleaching

Method of measurement

Disclosing agent

Secondary outcomes

empty

Intervention groups

1

Description

patients ,Before starting treatment:, the required explanations about stages of treatment will be provided to patients and written consent will be obtained The dates of the attendance of the participants in the various

meetings will be given in writing to them. In order to improve the oral health condition, a soft toothbrush and identical toothpastes and floss will be given to each patient. The same technique of brushing (Bass technique) and the same way of flossing will be trained (3 times a day for brushing teeth at correct times, noon and night, and floss once a night); and They should refrain from using other oral hygiene products. Patients will be required to refrain from eating any colorful drinks, such as tea, coffee, Nescafé, and wine during the bleaching process. At this stage, gingival health indicators including sulcus bleeding index and gingival index and plaque index will be measured. For each patient a prophylaxis is performed with oil-free prophylactic paste in order to omit the foreign pigments (by the student). Each patient will receive Alginate templates (by the student) and after confirming the template's correctness by the supervisor, chalk cast is immediately prepared after molding (by the student). The patient is notified about the next appointment. Physical surfaces of teeth is excluded in gypsum casts with a distance of 0.5 mm from gingival margin to incisal block (it is done by the library technician). In next appointment, patient's special tray is tested in his mouth and checked in relation to accordance with the teeth and gum margin. If not complied, it is made again. Maintenance training of the tray is presented during treatment. Bleaching tube jell is carbamida proxide 16% (whiteness perfect (FGM Dental-products, Joinville, Sc, Brazil). The tube jell is given to each patient the same day with its applying instructions. The time to apply is 4 hours a day in tray until 14 days. The instructions are presented both orally and in writing. All of these patients after treatment: The patient refers back after 14 days and SBI and PI and GI measured again and compared with data of before treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Restorative Dentistry Department, Dental College of Zahedan

Full name of responsible person

Doctor Tabtabayie Somaye

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Doctor Rafighdoost Hooshang

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mohammad javad Asgharzadeh

Position

Dentistry student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Position

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Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Doctor Tabatabayie Somaye

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available