Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessing the effect of a desensitizing gel used before home bleaching on tooth sensitivity in 18 to 30 years old women: A clinical trial study

Protocol summary

Summary

The purpose of this clinical trial study is evaluation the effect of using anti sensitivity gel befor home bleaching on tooth sensitivity. Patients were chosen between women aged 18 – 30 years old who recourse to dentistry college and had not any restoration or caries. Patient who had history of tooth sensitivity or bleaching treatment, removed from study. Sample size of each group was determined 15 person, 30 person in total. Primary tooth color, determined and recorded by devise (easy shade). Special home tray was made for each person. Trial gels including: placebo (control group) and anti sensitivity (intervention group) was used in similar tubes (for being double blind) by supervisor. Patients divided in A or B groups randomly. They should put gels in their mouth with the tray half hour befor using bleaching gel, then wash the tray and their mouth and use carbamide peroxide 16% (FGM) bleach gel, 4 hours in a day, during 14 days. For evaluation the level of tooth sensitivity, patients will asked to record probable pain level in day 1, 4, 7 and 14 after starting bleaching.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021032484N1**
Registration date: **2017-04-21, 1396/02/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-21, 1396/02/01

Registrant information

Name

Somayeh Somaye

Name of organization / entity

Dentistary

Country

Iran (Islamic Republic of)

Phone

+98 915 341 6206

Email address

somayehtabatabaei@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

private

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-04-19, 1396/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of a desensitizing gel used before home bleaching on tooth sensitivity in 18 to 30 years old women: A clinical trial study

Public title

Assessing the effect of a desensitizing gel used before home bleaching on tooth sensitivity in 18 to 30 years old women: A clinical trial study

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Women ages between 18 - 30 ; Natural anterior teeth with A2, B2, C2, D2 shade and darker ; At least 24 teeth be present ; Without any anterior restoration ; Good oral hygiene ; Patient consent exclusion criteria: Patient with caries. ; Patient with

gingivitis or periodontal disease. ; Patient with root exposure teeth. ; Patient with cervical lesions.; People who have orthodontic appliance. ; People who used to have tooth sensitivity to cold and hot or feel sensitivity with puar experiment. ; Using any anti sensitivity ingredients in past 3 months. ; Pregnant and milch women. ; Calculus existent. ;. People who take bleaching treatment before. 11. People who smoke ;. People with has teeth color change influence from fluorosis and tetracycline.

Age
No age limit
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
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
Zahedan University of Medical Sciences, Doctor Hesabi Sq. Zahedan, Iran
City
Zahedan
Postal code
009817699693
Approval date
2017-01-01, 1395/10/12
Ethics committee reference number
IR. ZAUMS. REC.1395.82

Health conditions studied

1

Description of health condition studied
Dental sensitivity after bleaching
ICD-10 code
Z40,Z54
ICD-10 code description
Persons encountering health services for specific procedures and health care

Primary outcomes

1

Description
Dental sensitivity
Timepoint
1 to 14 days after start bleaching
Method of measurement
Record on questionnaire by patient

Secondary outcomes

1

Description
Dental pain
Timepoint
1 to 14 days after start bleaching
Method of measurement
Record on questionnaire by patient

Intervention groups

1

Description
Use of desensitizing gel with bleaching gel (Intervention group)
Category
Treatment - Drugs

2

Description
Use of Placebo gel with bleaching gel (Control group)
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 Tabatabaei Somayeh
Street address
Dental College of Zahedan University of Medical Sciences, Azadegan St. Zahedan, Iran
City
Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person
Doctor Rafighdoost Hooshang

Street address
Zahedan University of Medical Sciences, Doctor Hesabi Sq. Zahedan, Iran

City
Zahedan

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Zahedan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Dental College of Zahedan University of Medical Sciences

Full name of responsible person
Madani Seyed Mohamadreza

Position
Dentistry student

Other areas of specialty/work

Street address
Dental College of Zahedan University of Medical Sciences, Azadegan St. Zahedan, Iran

City
Zahedan

Postal code
9817699693

Phone
+98 54 3341 4004

Fax

Email
mohamadreza.madani.mm@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Dental College of Zahedan University of Medical Sciences

Full name of responsible person
Doctor Tabatabaei Somayeh

Position
Assistant Professor of Restorative dentistary Department, Dental College of Zahedan University of Me

Other areas of specialty/work

Street address
Dental College of Zahedan University of Medical Sciences, Azadegan St. Zahedan, Iran

City
Zahedan

Postal code
9817966993

Phone
+98 54 3341 4004

Fax

Email
somayehtabatabaei@zaums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Dental College of Zahedan University of Medical Sciences

Full name of responsible person
Doctor Tabatabaei Somayeh

Position
Assistant Professor of Restorative Dentistry Department, Dental College of Zahedan University of Med

Other areas of specialty/work

Street address
Dental College of Zahedan University of Medical Sciences, Azadegan St. Zahedan, Iran

City
Zahedan

Postal code

Phone
+98 54 3341 4004

Fax

Email
somayehtabatabaei@zaums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty