

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Assessing the effect of a desensitizing gel used before home bleaching on color change (A clinical trial study)

Protocol summary

Summary

The purpose of this clinical trial study is evaluation the effect of using anti sensitivity gel before home bleaching on color change. 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 before 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 color change, patients will asked to record color change level in day 14,30,90,180 after starting bleaching.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051332484N2**

Registration date: **2017-08-19, 1396/05/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-19, 1396/05/28

Registrant information

Name

Somayeh Somaye

Name of organization / entity

Dentistry

Country

Iran (Islamic Republic of)

Phone

+98 915 341 6206

Email address

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Recruitment status

Recruitment complete

Funding source

Dental College of Zahedan University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-07-20, 1396/04/29

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 color change (A clinical trial study)

Public title

Assessing the effect of a desensitizing gel used before home bleaching on color change (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 pur 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

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

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**Approval date**

2017-03-05, 1395/12/15

Ethics committee reference number

IR.ZAUMS.REC.1395.281

Health conditions studied**1****Description of health condition studied**

Dental color change 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 color change

Timepoint

dental color change after 6 month

Method of measurement

determine dental color with easy shade

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**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

Dr Somaye Hoseini Tabatabaei

Position

Assistant Professor of Restorative dentistry
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Other areas of specialty/work**Street address**

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Person responsible for scientific

inquiries

Contact**Name of organization / entity**

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

Dr Somayeh Tabatabaei

Position

Dentistary

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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