

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 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 before 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 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 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

Dentistry

##### 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 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**

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**

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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**

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**

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## 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**

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## Person responsible for updating data

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Doctor Tabatabaei Somayeh

**Position**

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## 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*