

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Clinical evaluation of the effect of pH values of Hydrogen peroxide (35 %) on the ability of whitening teeth in office bleaching technique

#### Protocol summary

##### Summary

The aim of research: clinical study of changing the bleaching agent's pH for improving the color of discolored teeth. Inclusion criteria: dark teeth, absence of cracks and decay. Exclusion criteria: dental fluorosis. The study population and sample size: This study performs on 36 patients who voluntarily for bleaching. Intervention study and time: Patients divided randomly into three groups during 1 year. Patients receive one visit office bleaching 45 minutes treatment with 35% hydrogen peroxide at pH 8 and 10 and in the control group, pH is 6.4. The primary outcome: tooth whitening and sensitivity.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016111030813N1**  
Registration date: **2017-01-15, 1395/10/26**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-01-15, 1395/10/26

##### Registrant information

###### Name

Sahar Zeraatkar Davani

###### Name of organization / entity

Yazd University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3823 7792

###### Email address

drzeraatkar.s@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

YAZD University of Medical Sciences

##### Expected recruitment start date

2017-03-19, 1395/12/29

##### Expected recruitment end date

2017-03-19, 1395/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical evaluation of the effect of pH values of Hydrogen peroxide (35 %) on the ability of whitening teeth in office bleaching technique

##### Public title

evaluation of tooth whitening

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: adult patients with maxillary anterior teeth with a dark color;with discoloration caused by tetracycline or other discolorations can be treated with bleaching method;Dental leave absence; lack of wide labial surface of tooth-colored restorations; periapical lesion and absence of crowns and tooth sensitivity before treatment; lack of exposed roots or missing enamel;no caries and abrasion and attrition; not in pregnancy and lactation. Exclusion criteria: patient's unwillingness to participate in the study; patients with teeth discolorations caused by fluorosis; teeth with root canal therapy.

##### Age

No age limit

##### Gender

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 36

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Yazd University of Medical Sciences

**Street address**

Bahonar Square

**City**

Yazd

**Postal code****Approval date**

2016-09-22, 1395/07/01

**Ethics committee reference number**

IR.SSU.REC.1395.172

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

Posteruptive colour changes of dental hard tissues

**ICD-10 code**

K03.7

**ICD-10 code description**

Posteruptive colour changes of dental hard tissues

**Primary outcomes****1****Description**

ph

**Timepoint**

weekly

**Method of measurement**

Numerical scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

control group:bleaching with ph 6/4 duration of treatment 45 minutes apply the material on tooth

**Category**

Treatment - Other

**2****Description**

intervention group:bleaching with ph 8 duration of treatment 45 minutes apply the material on tooth

**Category**

Treatment - Other

**3****Description**

intervention group:bleaching with ph 10 duration of treatment 45 minutes apply the material on tooth

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Yazd University of Dentistry

**Full name of responsible person**

Sahar Zeraatkar Davani

**Street address**

Dahe Fajr Boulevard

**City**

Yazd

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Hasan Mozaffari

**Street address**

Bahonar Square

**City**

Yazd

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd 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**

Yazd University of Dentistry

**Full name of responsible person**

Sahar Zeraatkar

**Position**

Resident of Operative Dentistry

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**Position**

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**Other areas of specialty/work****Street 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*