Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 performes 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

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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
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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