Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of green Kemphor mouthwash versus chlorhexidine mouthwash on the tooth staining and gingivitis in patients undergoing oral surgery or periodontal treatment: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of green Kemphor mouthwash versus chlorhexidine mouthwash on the tooth staining and gingivitis in patients undergoing oral surgery or periodontal treatment

Design

This is a randomized clinical trial, phase II, in which 38 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients undergoing oral surgery or periodontal treatment and will refer to the School of Dentistry in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through block randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Patients needing chlorhexidine mouthwash after oral surgery or periodontal treatment, Plaque index greater than or equal to 30% Exclusion criteria: Pregnancy, Using cigarette of narcotic drugs, Consuming at least three times a day tea, coffee or soda, Use of toothpaste containing chlorhexidine or anti-plaque and bleaching agents

Intervention groups

Intervention group: Green Kemphor mouthwash (manufacture by Kemphor Company) 15 ml twice daily for 2 weeks, and then 4-day washout period (not using mouthwash), and then chlorhexidine mouthwash (manufactured by Iran Najo Company) 15 ml twice daily for 2 weeks Control group: Chlorhexidine mouthwash (manufactured by Iran Najo Company) 15 ml twice daily for 2 weeks, and then 4-day washout period (not using mouthwash), and then green Kemphor mouthwash (manufacture by Kemphor Company) 15 ml twice daily for 2 weeks

Main outcome variables

Primary outcome: Gingivitis, tooth staining

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N327**
Registration date: **2019-12-28, 1398/10/07**
Registration timing: **prospective**

Last update: **2019-12-28, 1398/10/07**
Update count: **0**

Registration date

2019-12-28, 1398/10/07

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of green Kemphor mouthwash versus chlorhexidine mouthwash on the tooth staining and gingivitis in patients undergoing oral surgery or periodontal treatment: a randomized clinical trial

Public title

Effect of green Kemphor mouthwash versus chlorhexidine mouthwash on the tooth staining and gingivitis in patients undergoing oral surgery or periodontal treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years, Patients needing chlorhexidine mouthwash after oral surgery or periodontal treatment, Plaque index greater than or equal to 30%

Exclusion criteria:

Pregnancy, Using cigarette of narcotic drugs, Consuming at least three times a day tea, coffee or soda, Use of toothpaste containing chlorhexidine or anti-plaque and bleaching agents

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-11-23, 1398/09/02

Ethics committee reference number

IR.UMSHA.REC.1398.674

Health conditions studied

1

Description of health condition studied

Gingivitis

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes

1

Description

Gingivitis

Timepoint

Before the intervention and 2 and 4 weeks after that

Method of measurement

By physical examination

2

Description

Tooth staining

Timepoint

Before the intervention and 2 and 4 weeks after that

Method of measurement

By physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Green Kemphor mouthwash (manufacture by Kemphor Company) 15 ml twice daily for 2 weeks, and then 4-day washout period (not using mouthwash), and then chlorhexidine mouthwash (manufactured by Iran Najo Company) 15 ml twice daily for 2 weeks
Category
Treatment - Other

2

Description
Control group: Chlorhexidine mouthwash (manufactured by Iran Najo Company) 15 ml twice daily for 2 weeks, and then 4-day washout period (not using mouthwash), and then green Kemphor mouthwash (manufacture by Kemphor Company) 15 ml twice daily for 2 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Dentistry in Hamadan city
Full name of responsible person
Fetemeh Olad
Street address
School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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info.research@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Fetemeh Olad
Position
Dentistry Student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Periodontics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available