

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 or 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)

Phone

+98 81 1838 0090

Email address

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 Kempfor 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 Kempfor 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 or 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.

City

Hamadan

Province

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Postal code

6517838695

Phone

+98 81 3838 0572

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fatemeolad.1994@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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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School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Amir Arsalan Hooshyarfard

Position

Periodontics

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Dr.A.Hooshyarfard@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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