

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

The comparison between the effect of the Hajji's Spray and chlorhexidine spray on the control of dental plaque : a Randomize Triple-Blind Controlled Phase-IIB Trial

Protocol summary

Summary

The aim of this clinical trial was to evaluate the efficacy of a new formula named "Hajji's spray" in controlling the dental plaque formation in comparison to the chlorhexidine spray as a gold standard. Methods. Design: A randomized, triple-blind, cross-over clinical trial employed two 5-day trial periods without mechanical oral hygiene intervention. Participants: In total 26 employee between 21 to 45 years old from 35 volunteers (mean age 26 ± 7.2 years). Intervention: Hajji's spray (intervention) and chlorhexidine spray (active control), was used twice daily (morning at awaking and evening before retiring). A 7-day washout-period was used between trial periods. Main outcome measures: Turesky modification of Quigly and Hein index was used to assess plaque formation. At the end of each test period, subjects were asked to evaluate the taste used products.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112188453N1**

Registration date: **2012-01-19, 1390/10/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-01-19, 1390/10/29

Registrant information

Name

Mohamadreza Abrishami

Name of organization / entity

Dental School of Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2212 3112

Email address

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Recruitment status

Recruitment complete

Funding source

Dental Research Center Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2011-01-05, 1389/10/15

Expected recruitment end date

2011-03-21, 1390/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between the effect of the Hajji's Spray and chlorhexidine spray on the control of dental plaque : a Randomize Triple-Blind Controlled Phase-IIB Trial

Public title

Anti-Plaque Efficacy of the Hajji's Spray

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: having at least 24 teeth Exclusion criteria: removable denture ; orthodontic appliance ; periodontal pocket grater than 4 mm ; attachment loss grater than 2 mm ; having pothological lesion ; medical or dental historical complication

Age

From **21 years** old to **46 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Dental Research Center Shahid Beheshti University of Medical Sciences

Street address

Dental Research Center Shahid Beheshti University of Medical Sciences, Evin, Tehran.

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

01-27-395

Health conditions studied

1

Description of health condition studied

Microbial Dental Plaque

ICD-10 code

k05.6

ICD-10 code description

Periodontal disease, unspecified

Primary outcomes

1

Description

assesment of dental plaque

Timepoint

at the beginning of study and 5 days after intervention

Method of measurement

Turesky modification of Quigley and Hein index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Hajji's spry was used twice daily (morning at awaking and evening before retiring)

Category

Prevention

2

Description

Intervention group 2: Chlorhexidine Spray was used twice daily (morning at awaking and evening before retiring)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Street address

Dental School of Shahid Beheshti University of Medical Sciences, Evin, Tehran.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dental School of Shahid Beheshti University of Medical Sciences.

Full name of responsible person

mrs.zoghi

Street address

Dental School of Shahid Beheshti University of Medical Sciences, Evin, Tehran.

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

Dental School of Shahid Beheshti 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**

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Position

Dentistry student

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Web page 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