Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial of comparison of efficacy of Halita mouthrine with chlorhexidine mouthrine in reducing oral malodor in patients with halitosis in 7-day consumption

Protocol summary

Summary

The purpose of this study is to compare the efficacy of two chlorhexidine and Halita mouthrinses in reducing bad breath in patients referring to the Department of Oral Medicine at Tabriz University of Medical Sciences. Inclusion criteria: Organoleptic score (OLS) of over 2. Exclusion criteria: Alcohol and tobacco use; Systemic diseases; Medications that cause dry mouth; Consumption of antibiotics in the previous two weeks; Pocket depth greater than 6 mm; Eating spicy foods, onion, and garlic 48 hours prior to the examination; Use of orthodontic appliances (fixed or removable) and removable dental prosthesis; Allergy or any undesirable reactions to either of test mouthrinses. It should be noted that, during the study period, the participants did not receive dental procedures such as scaling, restoration, etc. and thus their oral health conditions were unchanged. The most important issue in treatment of bad breath is to identify the cause in order to eliminate it. An easy and low-cost way is to administer health protocols that involve the use of toothbrush, dental floss, and mouthwash. Chemical methods such as using mouthwashes are complement to mechanical methods. A large number of studies on different types of mouthwashes such as chlorhexidine, cetylpyridinium chloride, and zinc have been performed. 50 samples were randomly selected and divided into two groups of 25, with consideration for the drop-out in the current triple-blind randomized controlled clinical trial. Halita (containing 0.05% chlorhexidine, 0.05% cetylpyridinium chloride, and zinc) and chlorhexidine moutrinses (both provided by Rozhin Co., Tabriz, Iran) were prepared in 140 ml volume for 7-day use (14 doses) in blindly marked similar containers. Oral and written instructions of using the mouthrinse were given to the patients. After 7 days, patients in both groups were examined to evaluate the effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121520314N1**
Registration date: **2015-02-23, 1393/12/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-23, 1393/12/04

Registrant information

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Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Rozhin Co.

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical trial of comparison of efficacy of Halita mouthrine with chlorhexidine mouthrine in reducing oral malodor in patients with halitosis in 7-day consumption

Public title
Comparison of efficacy of Halita mouthrine with chlorhexidine mouthrine in reducing oral malodor in patients with oral malador

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria: Organoleptic score (OLS) of over 2. Exclusion criteria: Alcohol and tobacco use; Systemic diseases; Medications that cause dry mouth; Consumption of antibiotics in the previous two weeks; Pocket depth greater than 6 mm; Eating spicy foods, onion, and garlic 48 hours prior to the examination; Use of orthodontic appliances (fixed or removable) and removable dental prosthesis; Allergy or any undesirable reactions to either of test mouthrinses. It should be noted that, during the study period, the participants did not receive dental procedures such as scaling, restoration, etc. and thus their oral health conditions were unchanged.

Age
From **17 years** old to **26 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Daneshgah street

City
Tabriz

Postal code

Approval date
2013-10-25, 1392/08/03

Ethics committee reference number
939

Health conditions studied

1

Description of health condition studied
Oral halitosis

ICD-10 code
R19.6

ICD-10 code description
Halitosis

Primary outcomes

1

Description
Oral halitosis

Timepoint
before intervention and after 7 days of intervention

Method of measurement
Organoleptic measurement

Secondary outcomes

empty

Intervention groups

1

Description
0.05% chlorhexidine mouth rinse in 140 ml volume for 7-day use (14 doses) 10 ml for one dose.

Category
Treatment - Drugs

2

Description
Halita(containing 0.05% chlorhexidine, 0.05% cetylpyridinium chloride, and zinc) mouth rinse in 140 ml volume for 7-day use (14 doses) 10 ml for one dose.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz University of Medical Sciences

Full name of responsible person

Dr Zahra Jamali
Street address
Daneshgah street
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, faculty of dentistry, Tabriz University of Medical Sciences
Full name of responsible person
Dr Naser Aminabady
Street address
Daneshgah street
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Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, faculty of dentistry, Tabriz 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

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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