

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the efficacy of two fluoride mouthrinses on Streptococcus mutans of saliva

Protocol summary

Summary

Introduction: Two common mouth rinses in markets are Oral-B solution and Irsha solution. The goal of this study is the comparison of the efficacy of Oral-B and Irsha fluoride mouth rinses on Streptococcus mutans. This is a randomized, single blind trial. 60 healthy girl students studying in high school with no history of taking antibiotics during recent 6 months, good oral health (at least two times of tooth brushing a day), and without rampant caries will recruit. Exclusion criteria are discontinuation of cooperation during study, and also involvement by any kind of disease and subsequent antibiotic administration during study. These girls are completely aware about the contribution in the research program and written informed consent is taken from them. These 60 students randomly allocated into two equal groups of 30 individuals. Intervention is consumption of Oral-B and Irsha mouth rinse ,so Oral-B mouth rinse is given to one group and Irsha mouth rinse is given to another group and they are asked to use mouth rinse as long for 4 weeks, twice a day(before tooth brushing ,after breakfast and dinner .Outcome measure is counting colonies of Streptococcus mutans, so saliva of each person is collected before and after using mouth rinse and is sent to laboratory for microbial cultures. Finally data is analyzed by T-test in the 0.95 confidence.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103085998N2**
Registration date: **2011-05-11, 1390/02/21**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-05-11, 1390/02/21

Registrant information

Name

Romina Mazaheri

Name of organization / entity

Islamic Azad University Khorasgan Branch

Country

Iran (Islamic Republic of)

Phone

00983115354053 ; 00989133135708

Email address

r.mazaheri@khuisf.ac.ir

Recruitment status

Recruitment complete

Funding source

Costs have been payed by student of dentistry(Azade Tajalli)

Expected recruitment start date

2004-10-22, 1383/08/01

Expected recruitment end date

2006-10-23, 1385/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of two fluoride mouthrinses on Streptococcus mutans of saliva

Public title

Efficacy of mouthrinses in prevention of caries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria :agreement and perfect cooperation of

contributors, absence of any systemic disorders ,no antibiotic coverage during recent 6 months ago, good oral health(at least two times of toothbrushing a day), uninvolved to rampant caries, absence of any orthodontic appliance. Exclusion criteria: discontinuation of cooperation during study ,involvement by any kind of disease during study,consumption of antibiotics during study

Age

From **15 years** old to **15 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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**

School of Dentistry, Islamic Azad University
Khorasgan Branch

Street address

Khorasgan Branch, Islamic Azad University -
Arghavanieh st -Jey st -Isfahan

City

Isfahan

Postal code**Approval date**

2004-04-23, 1383/02/04

Ethics committee reference number

23810201832001

Health conditions studied**1****Description of health condition studied**

microbiology of saliva

ICD-10 code

K00-K93

ICD-10 code description

Diseases of oral cavity, salivary glands and jaws

Primary outcomes**1****Description**

number of colonies of Streptococcus mutans

Timepoint

before intervention,4 weeks after intervention

Method of measurement

visual counting the number of colonies of Streptococcus mutans

Secondary outcomes

empty

Intervention groups**1****Description**

consumption of Irsha mouthrinse (15 cc of mouthrinse for 30 seconds,2 times a day,for 4 weeks)

Category

Prevention

2**Description**

consumption of Oral-B mouthrinse (15 cc of mouthrinse for 30 seconds,2 times a day,for 4 weeks)

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Zandizadeh ,boarding high school

Full name of responsible person**Street address****City**

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tajalli

Full name of responsible person

Azade Tajalli

Street address

Khorasgan Branch, Islamic Azad University -
Arghavanieh st -Jey st -Isfahan

City

isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tajalli

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

Islamic Azad University Khorasgan Branch

Full name of responsible person

Romina Mazaheri

Position

Assistant Professor, Department of Pediatrics, School of Dentistry, Islamic Azad University Khorasgan

Other areas of specialty/work

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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