

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Evaluation of the modified oral microflora stability using chlorhexidine and probiotic in 6-12 years old children

#### Protocol summary

##### Summary

The aim of this randomized controlled study was to investigate the effects of chlorhexidine and probiotic on the modified oral microflora stability. 105 children aged 6-12 years old were assigned into one of following groups. Group 1 received chlorhexidine, 0.12% mouthwash twice daily for 2 weeks; group 2 received probiotic yogurt containing Lactobacilli at a concentration of  $2 \times 10^8$  CFU/g for 3 weeks; and group 3 received chlorhexidine 0.12% mouthwash twice daily for 2 weeks and after 24 hours they received probiotic yogurt containing Lactobacilli at a concentration of  $2 \times 10^8$  CFU/g for 3 weeks. Salivary Streptococcus mutans and Lactobacilli were counted one day, one week, and five weeks after each intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138902183893N1**

Registration date: **2009-07-20, 1388/04/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2009-07-20, 1388/04/29

##### Registrant information

###### Name

Naser Aasl Aminabadi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1335 5965

##### Email address

n-aminabadi@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2009-07-20, 1388/04/29

##### Expected recruitment end date

2009-09-30, 1388/07/08

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the modified oral microflora stability using chlorhexidine and probiotic in 6-12 years old children

##### Public title

Evaluation of the modified oral microflora stability using chlorhexidine and probiotic in 6-12 years old children

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: No systematic disease, receiving no medications, not receiving any antibiotics or xylitol-containing chewing gums within 4 week prior to the study Exclusion criteria: salivary SM count lower than 105CFU/ml

##### Age

From **6 years** old to **12 years** old

##### Gender

Both

##### Phase

4

##### Groups that have been masked

No information

### Sample size

Target sample size: **105**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee Research on Humans, Tabriz  
University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences, Tabriz, Iran

##### City

Tabriz

##### Postal code

#### Approval date

2010-04-20, 1389/01/31

#### Ethics committee reference number

893

## Health conditions studied

### 1

#### Description of health condition studied

Dental carries

#### ICD-10 code

k02, k02.3

#### ICD-10 code description

dental carries, arested dental carries, other dental  
carries,dental carries unspecified

## Primary outcomes

### 1

#### Description

salivary Streptococcus mutans counts

#### Timepoint

at 24-hour, one-week, and five-week intervals after  
cessation of probiotic

#### Method of measurement

Saliva sampling and microbial evaluation

## Secondary outcomes

### 1

#### Description

Lactobacilli counts

#### Timepoint

at 24-hour, one-week, and five-week intervals after  
cessation of probiotic

#### Method of measurement

Saliva sampling and microbial evaluation

## Intervention groups

### 1

#### Description

chlorhexidine 0.12% mouthwash twice daily for 2 weeks;  
+ probiotic yoghurt containing Lactobacilli at a  
concentration of  $2 \times 10^8$  CFU/g for 3 weeks

#### Category

Treatment - Drugs

### 2

#### Description

received chlorhexidine 0.12% mouthwash twice daily for  
2 weeks

#### Category

Treatment - Drugs

### 3

#### Description

probiotic yoghurt containing Lactobacilli at a  
concentration of  $2 \times 10^8$  CFU/g

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Pediatric Dentistry, School of Dentistry

##### Full name of responsible person

##### Street address

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Naser Asl Aminabadi

##### Street address

Department of Paediatric Dentistry, School of

Dentistry, Tabriz University of Medical Sciences,

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

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

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Akram Ebrahimi

**Position**

DDS, Postgraduate student

**Other areas of specialty/work**

**Street address**

Department of Pediatric Dentistry, School of Dentistry, Tabriz University of Medical Sciences

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1335 5969

**Fax**

**Email**

ebrahimi\_pd@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

School of Dentistry, Tabriz University of Medical

**Full name of responsible person**

Naser Asl Aminabadi

**Position**

DDS, MSc, Associate professor

**Other areas of specialty/work**

**Street address**

Department of Pediatric Dentistry, School of Dentistry, Tabriz University of Medical Sciences

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1335 5965

**Fax**

+98 41 1334 6977

**Email**

aslaminabadi@Gmail.comn-aminabadi@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

School of Dentistry, Tabriz University of Medical Sciences

**Full name of responsible person**

Naser Asl Aminabadi

**Position**

DDS, MSc, Associate professor

**Other areas of specialty/work**

**Street address**

Department of Pediatric Dentistry, School of Dentistry, Tabriz University of Medical Sciences

**City**

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+98 41 1334 6977

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aslaminabadi@Gmail.comn-aminabadi@yahoo.com

**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*