

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Preparation of mouthrinse from extract of aerial part of zataria multiflora & frankincense as well as evaluation of their clinical effects on oral and dental healthcare's indexes.

#### Protocol summary

##### Summary

The purpose of this study is to provide herbal mouthwashes and compare their clinical effects with chlorhexidine mouthwash. This research is a double-blind randomized (using random permutation blocks) clinical trial done on 140 qualified volunteers referring to gum diseases department of Urmia University Medical Sciences. In this study, patients and researchers don't know the kind of intervention. In this way, after obtaining permission from the ethics committee and registering the research on the IRCT site, the researcher selects her own sample of adults who are eligible to enter in the study according to inclusion criteria including plaque index above 1.9, gingival index upper 1 and etc, and exclusion criteria including pregnancy, smoking, metabolic diseases and etc. Prepared herbal mouthrinses (tree types of mouthrinse respectively contain zataria multiflora extract, frankincense extract and both extract) and also chlorhexidine mouthrinse are packaged in quite similar containers. The necessary explanations about the study objectives will be given to the volunteers and the description sheet will be available to study. In the next step, the letter of consent and personal profile questionnaire is completed. One package containing one toothpaste, toothfloss and toothbrush is available to volunteers and they are thought how to use them correctly. In the next step, the people are randomly assigned to one of the groups, and according to assigned code, a special mouthrinse is given to them (A, B, C or D). Clinical examination to control the indexes to be considered in the study (plaque index, bleeding index, gingival index, teeth color index) will be done on the first day, fourteen and twenty one. Each week a phone call is made with the participants in the study and the next visit time and how to use the mouthrinse is remembered to them. Degree of satisfaction and possible adverse effects were measured by a questionnaire. The obtained

information will be analyzed using the SPSS24 software.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017072435263N1**

Registration date: **2017-08-31, 1396/06/09**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-08-31, 1396/06/09

##### Registrant information

##### Name

Zoleikha Khoshbakht

##### Name of organization / entity

Tabriz university medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3337 9528

##### Email address

khoshbakhtz@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Government

##### Expected recruitment start date

2017-08-30, 1396/06/08

##### Expected recruitment end date

2017-12-30, 1396/10/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Preparation of mouthrinse from extract of aerial part of zataria multiflora & frankincense as well as evaluation of their clinical effects on oral and dental healthcare's indexes.

**Public title**  
Preparation of mouthrinse from extract of aerial parts of zataria multiflora & frankincense as well as evaluation of their clinical effects on oral and dental diseases.

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: 1-plaq index above 1.9. 2-gingival index above 1. 3- not receiving any antibiotic or anti inflammatory drug in the long of this study and one month ago. 4- being literate. 5-having a call number. 6-the desire to participate in this study. Exclusion criteria: 1- systemic diseases. 2-using drugs that cause inflammation in the gum or exacerbate the gum diseases. 3-smoking . 4-use of other mouthrinses from four weeks ago . 5-sensitization to plant materials . 6-methabolic diseases(diabet,hyperthyroidism,etc). 7-pregnancy. 8- Doing any dental practices outside the scope of the study. 9-orthodontic patients.

**Age**

From **15 years** old to **55 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **140**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Other

**Other design features**

It is randomised using of random permutation blocks.

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

East azarbaijan university of medical sciences& health services

**Street address**

Tabriz,golbad street, tabriz university of medical sciences.

**City**

Tabriz

**Postal code**

5165665931

**Approval date**

2017-05-29, 1396/03/08

**Ethics committee reference number**

IR.tbzmed.REC.1396.161

**Health conditions studied**

**1**

**Description of health condition studied**

Oral& teeth health indexes.

**ICD-10 code**

ICD-1

**ICD-10 code description**

Certain infectious and parasitic diseases

**Primary outcomes**

**1**

**Description**

Bleeding index

**Timepoint**

Before intervention ,fourteen and twenty one day after intervention

**Method of measurement**

Salcos test and giving grade between 0-3 for it.

**2**

**Description**

Teeth color index

**Timepoint**

Before intervention and fourteen and twenty one day after intervention.

**Method of measurement**

Abservation and giving a grade between 0-3 for it.

**3**

**Description**

Gingivit index

**Timepoint**

Before intervention and fourteen and twenty one day after intevention

**Method of measurement**

Abservation and giving grade between 0-3 for it.

**4**

**Description**

Plaque index

**Timepoint**

Efore intervention and fourteen and twenty one day after intevention

#### **Method of measurement**

Chewing plaque search tablet and counting the number of plaques.

## **Secondary outcomes**

### **1**

#### **Description**

Possible adwers effects

#### **Timepoint**

Twenty one day after interaction

#### **Method of measurement**

Questionnaire

## **Intervention groups**

### **1**

#### **Description**

Using herbal mouthrinse contain zataria multiflora extract for 21day (twice in a day)as one of the intervention groupes.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Using mouthrinse contain chlorhexidine for 21day (twice in a day)as control group

#### **Category**

Treatment - Drugs

### **3**

#### **Description**

Using herbal mouthrinse contain both of zataria multiflora & frankincense extract for 21 day (twice In day) as one of the intervention group

#### **Category**

Treatment - Drugs

### **4**

#### **Description**

Using herbal mouthrinse contain frankincense extract for 21day (twice in a day) as one of the intervention group.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Gum diseases department urmia university of medical sciences

##### **Full name of responsible person**

Ehsan khashabi

#### **Street address**

Urmia,alborz street,gum diseases department urmia university of medical ccienes

#### **City**

Urmia

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

vice chncellor for research of tabriz university of medical sciences.

##### **Full name of responsible person**

Laleh khodaie dr

##### **Street address**

Tabriz,golbad street, tabriz university of medical sciences,traditional medicine department

##### **City**

Tabriz

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

vice chncellor for research of 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**

Zoleikha khoshbakht

##### **Position**

Phd candidate of traditional pharmacy

##### **Other areas of specialty/work**

##### **Street address**

Tabriz, abresane, golbad street

##### **City**

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##### **Postal code**

##### **Phone**

+98 44 3348 7232

##### **Fax**

##### **Email**

Khoshbakhtz@tbzmed.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Urmia university of medical sciences

**Full name of responsible person**

Ehsan khashabi dr

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Phd dr

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz university of medical sciences

**Full name of responsible person**

Zoleikha khoshbakht

**Position**

Phd candidate of traditional pharmacy

**Other areas of specialty/work**

**Street address**

Tabriz,golbad street

**City**

Tabriz

**Postal code**

**Phone**

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**Fax**

**Email**

**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*