

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Effect of ANSIL(Silver nanoparticles) to improve recurrent aphthous stomatitis: a double-blind clinical trial

#### Protocol summary

##### Study aim

Determining and comparing the effect of different doses of ANSIL solution on pain intensity and recovery time of recurrent aphthous stomatitis

##### Design

Due to the lack of previous studies in this field and the pilot nature of the present study, using the study of Amy L Whitehead et al. And considering the average effect size, 20 people in each group will be considered (total sample size 80 people)

##### Settings and conduct

This study is a double-blind, placebo-randomized study using ANSIL solution or placebo in people with symptomatic oral aphthous. Subjects are randomly assigned to intervention and control groups. Patients referred to Imam Reza Hospital of Tabriz University of Medical Sciences with signs and symptoms related to oral plaque through the entry/exit criteria and with informed written consent are included in the study or removed from it.

##### Participants/Inclusion and exclusion criteria

Patients with minor and solitary aphthous ulcers in the cheek and lip mucosa of both sexes in the age range of 18 to 40 years are included in this study. In this study, pregnant, lactating, systemic patients with herpetiform ulcers and major aphthous ulcers Or multiple minor for more than 4 days and patients who refuse to participate in the study are excluded from the study

##### Intervention groups

Intervention group1:20 patients with oral aphthous receive a solution of ANSIL at a dose of 0.5 twice a day/Intervention group2: 20 patients with oral aphthous receive a solution of ANSIL at a dose of 1 twice a day/Intervention group3: 20 patients with oral aphthous receive a solution of ANSIL at a dose of 2 twice a day  
Control group: 20patients with oral aphthous Treating in a way other than the mentioned procedure

##### Main outcome variables

Comparison of different doses of ANSIL solution on the

recovery time and pain intensity of recurrent oral aphthous

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190701044062N6**

Registration date: **2021-06-26, 1400/04/05**

Registration timing: **prospective**

Last update: **2021-06-26, 1400/04/05**

Update count: **0**

##### Registration date

2021-06-26, 1400/04/05

##### Registrant information

##### Name

manouchehr khoshbaten

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1334 3010

##### Email address

mkhoshbaten@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-06, 1400/04/15

##### Expected recruitment end date

2022-05-05, 1401/02/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effect of ANSIL(Silver nanoparticles) to improve recurrent aphthous stomatitis: a double-blind clinical trial

**Public title**

Effect of ANSIL on the aphthous

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Minor and solitary aphthous ulcers in the lip mucosa or cheek Age range 18 to 40 years

**Exclusion criteria:**

Pregnant Breastfeeding Patients with systemic disease Patients with herpetiform ulcers and multiple major or minor aphthous ulcers for more than 4 days Patients who refuse to participate in the study

**Age**

From **18 years** old to **40 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be performed using simple randomization using GraphPad software and by a secretary who does not interfere with other stages of the investigation. Blinding will be done by labeling the ointments as A, B, C, D that a person who is aware of the contents of each ointment is not present in other stages of the research and after statistical analysis of the contents of the ointment will be obtained.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

A solution that has an active ingredient in ANCIL with a solution that does not have a substance and is used as a placebo is completely identical in terms of the shape and size of the container, and the solution themselves do not differ in terms of odor and color, and are completely indistinguishable. (This action was taken by the pharmaceutical company). The important point is that the patient is told that the solution used for the patient may be medication or medication. Clinicians or outcome assessors and blind patients will be blinded.

**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 Medic

**Street address**

Central Office of Tabriz University of Medical Sciences  
Tabriz -Golghast St.- Azadi St.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Approval date**

2021-05-17, 1400/02/27

**Ethics committee reference number**

IR.TBZMED.REC.1400.179

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

recurrent aphthous stomatitis

**ICD-10 code**

K12.0

**ICD-10 code description**

Recurrent oral aphthae

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

Comparison of different doses of ANCIL and placebo solution on the recovery time of recurrent oral aphthous

**Timepoint**

80 patients will be divided into 4 groups of 20 and 3 groups of patients will receive doses of 0.5, 1, and 2 ANCIL solution. The fourth group will receive the basic formulation of the solution without active components. The duration of use of the solutions will be a maximum of 7 days. Then the duration of complete recovery of the oral aphthous in the groups will be compared.

**Method of measurement**

Different doses are compared based on the patient's clinical symptoms and observing the speed of oral aphthous recovery

## 2

### **Description**

Pain intensity in patients with recurrent oral aphthous

### **Timepoint**

On days 0, 5 and 7

### **Method of measurement**

VAS questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group:20 patients with oral aphthous receive a solution of ANCIL at a dose of 0.5 twice a day

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group: 20 patients with oral aphthous receive a solution of ANCIL at a dose of 1 twice a day

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Intervention group: 20 patients with oral aphthous receive a solution of ANCIL at a dose of 2 twice a day

#### **Category**

Treatment - Drugs

### 4

#### **Description**

Control group: 20patients with oral aphthous Treating in a way other than the mentioned procedure

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Imam Reza Hospital, Tabriz

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

Manouchehr Khoshbaten

##### **Street address**

Golgasht St, Tabriz

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166614766

##### **Phone**

+98 41 1334 3010

##### **Email**

mkhoshbaten@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Tabriz University of Medical Sciences

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

Mohammad Samiei

##### **Street address**

Golgasht Street

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166/15731

##### **Phone**

+98 41 3335 9680

##### **Email**

reasearch-vice@tbzmed.ac.ir

##### **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**

Public

##### **Domestic or foreign origin**

Domestic

##### **Category of foreign source of funding**

empty

##### **Country of origin**

##### **Type of organization providing the funding**

Academic

## **Person responsible for general inquiries**

#### **Contact**

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

Tabriz University of Medical Sciences

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

Ali Yousefipour

##### **Position**

medical student

##### **Latest degree**

Medical doctor

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

General Practitioner

##### **Street address**

No1026,East Second floor, Azarabadegan Ave, Third daneshgah Ave, Nasr Town

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5158375751

**Phone**

+98 41 3662 8155

**Email**

ali\_you\_2015@yahoo.co.uk

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Manouchehr Khoshbaten

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Adult digestive and liver

**Street address**

Golgasht Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166/15731

**Phone**

+98 41 1334 3010

**Email**

mkhoshbaten@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Yousefipour

**Position**

medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Postal code**

5158375751

**Phone**

0416628155

**Email**

ali\_you\_2015@yahoo.co.uk

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

A portion of the data will be shared.

**When the data will become available and for how long**

2023-2024

**To whom data/document is available**

Researchers and academic staffs

**Under which criteria data/document could be used**

For further studies

**From where data/document is obtainable**

Request via email

**What processes are involved for a request to access data/document**

Request via email

**Comments**