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 ANCIL 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 ANCIL 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 plague 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 ANCIL at a dose of 0.5 twice a day/Intervention group2: 20 patients with oral aphthous receive a solution of ANCIL at a dose of 1 twice a day/Intervention group3: 20 patients with oral aphthous receive a solution of ANCIL 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 ANCIL 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)

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+98 41 1334 3010

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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
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Golgasht St, Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Ali Yousefipour
Position
medical student
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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