Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Tetanus diphtheria(Td) booster vaccine effect on recovery and relapse of recurrent minor oral aphthous.

Protocol summary

Summary

This is a triple-blind clinical trial to compare the efficacy of the drug with placebo. Patients with recurrent minor oral aphthous are selected from dermatology clinic by a dermatologist. Inclusion criteria include; patients who have 1 to 3 minor(size:1-8 millimeters) oral aphthous, with at least one relapse per month, . Exclusion criteria include :establishment of anemia, HIV or Behcet's syndrome and recipients of tetanus-diphtheria(Td) vaccine in the last five years. Obtaining informed consent from the patients ,they are divided into two groups based on random numbers. At the time of relapse , a common treatment prescribed to both groups.(1 mg Colchicine tablet per day for 5 days). At the beginning of the study , a single dose of Tetanus diphtheria(Td) vaccine for one of the groups and one milliliter of injections of vitamin B-6 for other group will be administered in the deltoid region. Each of them will be examined in the event of problems at the injection site. Subjects will be followed for 6 months. Before and after the study, the number of aphthous, its pain intensity and its size, the intervals between relapses and the time required for its healing will be assessed. The assessment will be done by the patients themselves. Lesion size in millimeter , pain with a score of 0 to 10 and the interval between relapses and time to recovery will be measured in days. Data will be analyzed after 6 months.

General information

Acronym

Tetanus diphtheria(Td) booster vaccine effect on recovery and relapse of recurrent minor oral aph

IRCT registration information

IRCT registration number: **IRCT201501213989N1**
Registration date: **2016-01-03, 1394/10/13**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-01-03, 1394/10/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ardabil University of Medical science

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-12-01, 1394/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Tetanus diphtheria(Td) booster vaccine effect on recovery and relapse of recurrent minor oral aphthous.

Public title

Tetanus-diphtheria(Td) vaccine effect on recurrent minor oral aphthous.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 20 to 60 years old patients; who have 1 to 3 minor(1-8 millimeters) oral aphthous; with at least one relapse per month, Exclusion criteria :establishment of anemia; HIV or Behcet's syndrome ; recipients of tetanus-diphtheria(Td) vaccine in the last five years

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients are not aware of the content of what they injected . The nurse injected the drug is not aware of its content. Tracking the effectiveness of treatment is not aware of the type of treatment. Statistician is unaware of the content of the treatment groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Science

Street address

Kousar Minisity,Daneshghah Street,Ardabil

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Postal code

5618985991

Approval date

2014-10-18, 1393/07/26

Ethics committee reference number

Arums.REC.93.52

Health conditions studied

1

Description of health condition studied

Recurrent Aphthous stomatitis(minor)

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

Aphthous remission after treatment

Timepoint

At the beginning and end of the study

Method of measurement

Based on the judgment of those who have studied .Complete remission, partial remission, non-recovery

2

Description

The interval between the occurrence of aphthous

Timepoint

180 days

Method of measurement

One day(24 hours)

3

Description

The number of aphthous in each recurrence

Timepoint

180 days

Method of measurement

The number of aphthous

4

Description

Measuring pain intensity

Timepoint

180 days

Method of measurement

A score of 0 to ten according to one's own judgment

5

Description

Size of aphthous

Timepoint

180 days

Method of measurement

milimeter

Secondary outcomes

1

Description

Injection site reactions

Timepoint
Fifteen days after injection
Method of measurement
Physical examination in case of complications

Intervention groups

1

Description
In the intervention group, one mg of oral colchicine daily for 5 days plus a booster dose of ,Tetanus diphtheria(Td) vaccine is injected right deltoid region. In case of recurrent aphthous, oral colchicine one mg daily for 5 days ,repeated.
Category
Treatment - Drugs

2

Description
In the control group one milligram oral colchicine daily for five days plus a half cc of vitamin B6 as a placebo in right deltoid area injected. In case of recurrent aphthous, oral colchicine one mg daily for 5 days ,repeated.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Shahram Habibzadeh
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City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Ardabil University of Medical Sciences
Full name of responsible person
Mohsen Sagga.Director of Research and Technology
Street address
Kousar minisity ,Daneshghah street,Ardabil
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Ardabil
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research,Ardabil 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
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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