Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of phenytoin and triamcinolone on the minor aphthous ulcer

Protocol summary

Study aim
1-Determine and compare the middle score of the severity of irritation aphthous ulcer before intervention in two groups 2-Determine and compare the mean score of the maximum diameter aphthous ulcer before intervention in two groups 3-Determine and compare the mean score of the reduce pain and irritation aphthous ulcer in two groups 4-Determine and compare the mean score of the reduce size aphthous ulcer in two groups 5-Determine and compare the middle score of the severity of irritation aphthous ulcer before and after 3,5,7 days using ointment in two groups 6-Determine and compare the mean score of the maximum diameter aphthous ulcer before and after 3,5,7 days using ointment in two groups

Design
Double blind study in two groups with minimum sample size of 30 samples and patient in each group selected from encoded random numbers table

Settings and conduct
For double blinding, drugs is divided by pharmacologist to A and B, the doctor and patient are not aware of the type of drug

Participants/Inclusion and exclusion criteria
The age of the patient is between 20 and 40 years Less than a day from the onset of a wound Patient has not used any other treatment for the wound before referral Patients agree to cooperate with this research patient has not systemic disease related to aphthous lesion and there are no suspected signs of systemic disease associated with ulcer exclusion: Use of other medications plus ointment for treatment Do not use the medicine as recommended according to the patient Missing follow up Lesions in tonsils and 1/3 posterior of oral

Intervention groups
first group administration of Phenytoin; second group administration of Triadent on oral aphtous lesions and evaluation of the severity of pain, size of the wound and the recovery time before and after administration.

Main outcome variables
Evaluation of pain and burning symptoms and size of ulcer present in patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20081109001442N3**
Registration date: **2019-02-10, 1397/11/21**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-10, 1397/11/21**
Update count: **0**

Registration date
2019-02-10, 1397/11/21

Registrant information

Name
Hakimeh Ahadian

Name of organization / entity
Faculty of Dentistry, Yazd University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 35 1625 5881

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-21, 1397/08/30

Expected recruitment end date
2019-08-06, 1398/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of phenytoin and triamcinolone on the minor aphthous ulcer

Public title

Comparison of the effect of phenytoin and triamcinolone on the minor aphthous ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The age of the patient is between 20 and 40 years Less than a day from the onset of a wound Patient has not used any other treatment for the wound before referral Patients agree to cooperate with this research Patient has not systemic disease related to aphtouse lesion and there are no suspected signs of systemic disease associated with ulcers

Exclusion criteria:

Use of other medications plus ointment for treatment Do not use the medicine as recommended according to the patient Missing follow up Lesion in tonsils and 1/3 posterior of oral

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

60 patients who have been randomly assigned to numbers encoded using numbers, 30 patients using A drug(mucous adhesive phenytoin) and 30 patients using B drug(mucous adhesive triadent).

Blinding (investigator's opinion)

Double blinded

Blinding description

The ointment is divided by the pharmacist which is not known to the patient and physician

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

Dahe fajr boulevard, shahid sadoughi of dental university

City

Yazd

Province

Yazd

Postal code

89195165

Approval date

2019-01-05, 1397/10/15

Ethics committee reference number

IR.SSU.REC.1397.116

Health conditions studied

1

Description of health condition studied

Oral aphthous ulcer

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

recovery aphthous lesion

Timepoint

Evaluation of severity of pain and diameter of lesion and duration of recovery after 3 , 5 and 7 days using.

Method of measurement

VAS(Visual Analogue Scale) / measuring the wound by millimeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: mucus adhesive phenytoiin oint , three times a day, for a week

Category

Treatment - Drugs

2

Description
Intervention group: mucus adhesive triadent oint , three times a day, for a week
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental University of Shahid Sadoughi Yazd
Full name of responsible person
Yasaman Sabaghzadegan
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Fatemeh Khezri
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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
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Yasaman Sabaghzadegan
Position
Resident
Latest degree
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Person responsible for updating data

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Position
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available