Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation the effect nut meg biogel on recurrent aphthous stomatitis

Protocol summary

Summary

The purpose this study is to evaluate the effects of nut meg biogel on recurrent aphthous stomatitis .This is a randomized ,double - blind ,crossover clinical trial. Inclusion criteria:People with a history of minor oral aphthous lesions in the mucosa of the cheek or lip,at least fourPeriods per year ؛ The age group 18 to 50 years. Exclusion criteria:minor or multiple minor aphthous ulcers ؛ ulcers in other sites expect labial and buccal mucosa ؛ present of any systemic diseases that developed oral ulcers ؛ bechet disease؛ hematologic diseases ؛ taking chemotherapic drugs؛ pregnant and nursing weman.20 patients with recurrent aphthous stomatitis history are selected from the students of Babol university of medical sciences and patients referred to oral medicine department ,school of dentistry, Babol university of medical sciences. Each patient is monitored in four periods of aphthous ulcers and one period without treatment and just monitoring the ulcer and three periods with taking one of biogel, triamcinolone or nut meg biogel randomly .All patients are visited in 1st, 3rd, 5th, 7th and 10th days at each period.Primary outcomes include:Pain intensity(VAS) and ulcer size.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201603149271N5**
Registration date: **2016-05-05, 1395/02/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-05, 1395/02/16

Registrant information

Name

Ali Akbar Moghadamnia

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect nut meg biogel on recurrent aphthous stomatitis

Public title

Evaluation the effect of nut meg biogel on oral minor aphthous.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:People with a history of minor oral aphthous lesions in the mucosa of the cheek or lip,at least four courses per year ؛ The age group 18 to 50 years . Exclusion criteria:minor or multiple minor aphthous ulcers ؛ulcers in other sites expect labial and buccal mucosa؛ present of any systemic diseases that develope oral ulcers such as gastrointestinal disorders (crohn disease, ulcerative colitis)؛ bechet disease؛ Reiter

syndrome؛ hematologic diseases؛malnutrition؛ allergic condition؛ consumption of chemotrapic drugs ؛immunosupressive or systemic corticosteroids at past year؛ patients with any other mucosal؛ pregnant and nursing woman.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Babol University of Medical Sciences, Deputy of research & technology

Street address
University of Medical Sciences, Ganjafroz Street, Babol

City
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Postal code
4717641367

Approval date
2015-10-26, 1394/08/04

Ethics committee reference number
MUBABOL.REC.1394.160

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
ulcer size

Timepoint
1st, 3rd, 5th, 7th and 10th days

Method of measurement
gauge measurement

2

Description
pain intensity

Timepoint
firth, third,fifth,seventh and tenth days

Method of measurement
visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Nut meg biogel 3 times a day until recovery

Category
Treatment - Drugs

2

Description
Triamcinolone biogel 3 times a day until recovery

Category
Treatment - Drugs

3

Description
biogel 3 times a day until recovery

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Babol University of Medical Sciences, Department of Oral Medicine

Full name of responsible person
Simin Noori khanghah

Street address
Babol University of Medical Sciences, Ganjafroz Street, Babol

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Ali Bijani
Street address
University of Medical Sciences, Ganjafroz Street, Babol
City
Babol
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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