Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of therapeutic effects of Aloe vera gel on minor recurrent aphthous stomatitis (RAS)

Protocol summary

Summary

Aphthous ulcer is one of the commonest oral cavity diseases with no known effective treatment so far which could cause severe discomfort in patients. Aloe vera (A.V.) is a tropical plant with anti-inflammatory and immunostimulant effects which could be of benefit in diversity of wounds healings conditions. The aim of this study is to evaluate topically administered A.V. gel on oral cavity aphthous healing. As a double blind clinical trial,40 patients would be treated by either placebo or A.V. oral gel. The healing time (days after gel application), patients pain score, the lesion and its surrounding inflammation diameters would be recorded for 2 weeks. After decoding the gel containers, AV treated group's results would be compared to placebo ones and P<0.05 would be statistically considered significant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107277136N1**
Registration date: **2011-08-08, 1390/05/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-08-08, 1390/05/17

Registrant information

Name

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Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2010-04-04, 1389/01/15

Expected recruitment end date

2011-02-01, 1389/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effects of Aloe vera gel on minor recurrent aphthous stomatitis (RAS)

Public title

Therapeutic effects of Aloe Vera on canker sore

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Written consent 2) Age between 15-35 3) No systemic or oral cavity diseases except for RAS 4) Having singular minor recurrent aphtous on inner lips or cheeks since less than 48 h ago Exclusion Criteria: 1) Refusing to give written consent 2) Having any systemic or oral cavity diseases other than RAS minor 3) Aphthous stomatitis (major) 4) Having multiple RAS lesions in oral cavity 5) Pregnancy 6) Smoking

Age

From **15 years** old to **35 years** old

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Babol University of Medical Sciences ethics committee
Street address
BUMS, Ganje Afrooz avenue
City
Babol
Postal code
Approval date
2008-02-20, 1386/12/01
Ethics committee reference number
2436

Health conditions studied

1

Description of health condition studied
Recurrent aphthous stomatitis
ICD-10 code
K12.0
ICD-10 code description
Aphthous stomatitis (minor)r

Primary outcomes

1

Description
Stimulated pain score after
Timepoint
daily
Method of measurement
Visual Analogue Score

2

Description
Lesion and its surrounding inflammation diameters
Timepoint
Days: 0, 1, 3, 7 and 10
Method of measurement
Visual measurement using a metal caliper

Secondary outcomes

1

Description
Healing period
Timepoint
end of treatment
Method of measurement
VAS <2 and lesions less than 1 mm diameter

Intervention groups

1

Description
Administration of Aloe-Vera oral gel (2%): Using 50 ml pump-cap polystyrene containers the gel would be applied on the lesions 3 times a day for at least 10 days
Category
Treatment - Drugs

2

Description
Administration of Placebo (Lubricant oral gel containing 2% normal saline): Using 50 ml pump-cap polystyrene containers the placebo gel would applied on the lesions 3 times a day for at least 10 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Babol University of Medical Sciences, School of Dentistry
Full name of responsible person
Dr Ebrahim Zabihi
Street address
City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research; Babol University of Medical

Sciences

Full name of responsible person

Dr Neda Babaee

Street address

School of Dentistry

City

Babol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research; 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

Name of organization / entity

Babol University of Medcial Sciences

Full name of responsible person

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Position

Lecturer/PharmD,PhD

Other areas of specialty/work

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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