

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 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

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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 aphthous 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 Medical 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