

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Propolis gel versus placebo on wound treatment in patients with recurrent minor aphtous ulceration: a double-blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of Propolis gel versus orabase gel (placebo) on treatment of lissions in patients with recurrent minor aphtous ulcer **Design:** a double blind randomized clinical trial. **Setting and conduct:** The eligible patients with recurrent minor aphtous ulcers who will refer to Hamadan Dentistry School during the study period will be enrolled into the trial. **Inclusion criteria:** (a) age of 15 to 60 years; (b) having recurrent minor aphtous ulcers; (c) history of disease for more than one year with at least two recurrence a year; (d) having 1 to 6 ulceration if each episode; (e) less than 72 hours from the begging of the ulceration; (f) the duration of healing without medication is not more than 7 days; (g) the size of ulcers is not more than 1 cm. **Exclusion criteria:** (a) hypersensitivity to drug or plant; (b) treatment with immunosuppressive drugs during the last month; (c) using systemic antibiotic during the last two weeks; (d) using anti-inflammatory drugs or anti-histamine during the last month; (e) using any drug for treatment of aphtous ulcers during the last 72 hours; (f) having systemic diseases such as endocrine, immunologic, hematologic, metabolic, rheumatoid arteritis, and hormonal disorders; (g) during pregnancy or breastfeeding; complete or partial denture or unsuitable restoration of a tooth or appliance ortodency in close contact with aphtous ulcers; (h) cigarette smoking or drinking alcohol; (i) affected with major aphtous ulcers or herpetiform ulcers. **Intervention:** putting 1 cm in length of Propolis gel on aphtous ulcers 4 time a day for 6 days. **Control:** putting 1 cm in length of orabase gel (placebo) on aphtous ulcers 4 time a day for 6 days. **Primary outcome:** (a) measuring the pain severity before and 3 and 6 days after treatment by taking history; (b) measuring the diameter of lesions before and 3 and 6 days after treatment by physical examination. **Secondary outcome:** presence of erythema or exudates 3 and 6

days after treatment by physical examination.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411269014N49**

Registration date: **2014-12-02, 1393/09/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-02, 1393/09/11

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2014-11-26, 1393/09/05

Expected recruitment end date

2015-02-24, 1393/12/05

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Propolis gel versus placebo on wound treatment in patients with recurrent minor aphtous ulceration: a double-blind randomized clinical trial

Public title
Effect of Propolis gel versus placebo on wound treatment in patients with recurrent minor aphtous ulceration

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: (a) age of 15 to 60 years; (b) having recurrent minor aphtous ulcers; (c) history of disease for more than one year with at least two recurrence a year; (d) having 1 to 6 ulceration if each episode; (e) less than 72 hours from the begging of the ulceration; (f) the duration of healing without medication is not more than 7 days; (g) the size of ulcers is not more than 1 cm. Exclusion criteria: (a) hypersensitivity to drug or plant; (b) treatment with immunosuppressive drugs during the last month; (c) using systemic antibiotic during the last two weeks; (d) using anti-inflammatory drugs or anti-histamine during the last month; (e) using any drug for treatment of aphtous ulcers during the last 72 hours; (f) having systemic diseases such as endocrine, immunologic, hematologic, metabolic, rheumatoid arteritis, and hormonal disorders; (g) during pregnancy or breastfeeding; complete or partial denture or unsuitable restoration of a tooth or appliance ortodency in close contact with aphtous ulcers; (h) cigarette smoking or drinking alcohol; (i) affected with major aphtous ulcers or herpetiform ulcers.

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization: random assignment of the patients systematically one at a time to intervention and control groups. Blinding: both propolis gel versus orabase gel

(placebo) will be prepared in dark and similar containers thus patients will not be aware of the type of treatment they receive. In addition, the examiner who will examine the patients is another person that will not be aware of the type of intervention. Therefore, the trial will be run as double blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2014-11-25, 1393/09/04

Ethics committee reference number

D/P/16/35/9/4184

Health conditions studied

1

Description of health condition studied

aphtous ulcers

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

measuring the diameter of lesions

Timepoint

before and 3 and 6 days after treatment

Method of measurement

by physical examination

2

Description

measuring the pain severity

Timepoint

before and 3 and 6 days after treatment

Method of measurement

by taking history

Secondary outcomes

1

Description

presence of erythema or exudates

Timepoint

3 and 6 days after treatment

Method of measurement

by physical examination

Intervention groups

1

Description

putting 1 cm in length of Propolis gel on aphtous ulcers 4 time a day for 6 days

Category

Treatment - Drugs

2

Description

putting 1 cm in length of orabase gel (placebo) on aphtous ulcers 4 time a day for 6 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry School

Full name of responsible person

Azadeh Moslemkhani

Street address

Dentistry School, Shahid Fahmideh Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

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 the Technology, Hamadan
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

Dentistry School

Full name of responsible person

Azadeh Moslemkhani

Position

Dentistry student

Other areas of specialty/work

Street address

Dentistry School, Shahid Fahmideh Ave.

City

Hamadan

Postal code

Phone

+98 81 3838 1086

Fax

Email

freebird_a90@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Dentistry School

Full name of responsible person

Dr Sharmin Abdollahzadeh

Position

Oral disease specialist

Other areas of specialty/work

Street address

Dentistry School, Shahid Fahmideh Ave.

City

Hamadan

Postal code

Phone

+98 81 3838 1086

Fax

Email

shery13562002@yahoo.com

Web page address

Person responsible for updating data

Contact

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