Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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.
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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
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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
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

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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