

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of propolis and placebo in controlling the frequency of relapses in patients with recurrent aphthous stomatitis

Protocol summary

Summary

The purpose of this pilot study was to evaluate the potential of bee propolis in reducing the number of outbreaks of aphthous ulcers in patients with high recurrences. Participants in this trial was patients with confirmed clinical diagnosis of minor aphthous ulcers and they had at least once a month aphthous ulcer episode and a minimum interval of 2 weeks from previous treatment and drug use . patients with anaemia (based on their CBC (H1) and the hematologist consultation, blood disorders, lack of satisfaction to take part in research, Pregnancy, being under 8 years old and disabled, usage of drugs that may affect the immune system and history of previous allergy to propolis or other bees` products didn't participate in this research. In this randomized, triple blind study, 22 patients (12 case and 10 control) with minor aphthous stomatitis, referred to Oral Medicine Department of Mashad Faculty Of Dentistry from September 2011 until january2012were participated. Patients were assigned to take 500 mg of propolis or a placebo tablet daily. Subjects were examined every 2 weeks for at least 6 months. They reported a baseline ulcer frequency and were assessed biweekly for recurrence of ulcers, ulcer size, pain and burning. Results were recorded to determine if subjects had a decrease in outbreak frequency.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072214101N1**

Registration date: **2013-10-15, 1392/07/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-10-15, 1392/07/23

Registrant information

Name

farzad nazari

Name of organization / entity

mazandaran university of medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Oral and Maxillofacial Diseases Research Center of Mashahd University of Medical Sciences

Expected recruitment start date

2011-09-01, 1390/06/10

Expected recruitment end date

2012-01-01, 1390/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of propolis and placebo in controlling the frequency of relapses in patients with recurrent aphthous stomatitis

Public title

The effect of bee propolis in reducing the aphthous ulcers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1 - confirmed the clinical diagnosis of minor aphthous ulcers. 2 - At least once a month aphthous ulcer recurrence . 3 - a minimum interval of 2 weeks of previous treatment 4 - spontaneous healing wounds less than 2-1 weeks. Exclusion criteria: 1 - Patients with anemia (based on the trial CBC (H1) and the hematologist), blood disorders. 2 - Lack of patient's satisfaction. 3 - Patients who are pregnant, lactating, under 8 years old and disabled. 4-usage of drugs that may affect the immune system. 5- allergy to propolis.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad Faculty of Dentistry

Street address

Mashad Faculty of dentistry, opposite Mellat park,
Azadi square

City

Mashhad

Postal code

Approval date

2011-08-06, 1390/05/15

Ethics committee reference number

900097

Health conditions studied

1

Description of health condition studied

Recurrent Aphthous Stomatitis

ICD-10 code

k00-k14

ICD-10 code description

k12.0

Primary outcomes

1

Description

the frequency of recurrent aphthous stomatitis

Timepoint

monthly

Method of measurement

mean number of recurrence during a month

Secondary outcomes

1

Description

mean size of ulcers

Timepoint

Biweekly

Method of measurement

By caliper

2

Description

pain of ulcers

Timepoint

Biweekly

Method of measurement

VAS system

3

Description

time of healing

Timepoint

Biweekly

Method of measurement

mean number of days of healing of ulcers

Intervention groups

1

Description

case group of patients took a daily 500mg tablet of
Propolis for 6 months

Category

Treatment - Drugs

2

Description

control group of patients took one tablet of placebo a
day which have same shape as propolis tablet but
without the propolis for 6 months.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry

Full name of responsible person

Street address

Mashhad Faculty of Dentistry, Opposite mellat park,
azadi square

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oral and Maxillofacial Diseases Research Center of
Mashhad University of Medical Sciences

Full name of responsible person

Zahra Delavarian

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Mashhad Faculty of Dentistry, Opposite of Mellat Park,
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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

Oral and Maxillofacial Diseases Research Center of
Mashhad 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

Mashhad Faculty of Dentistry

Full name of responsible person

Zahra Delavarian

Position

Associated Professor of Oral Medicine

Other areas of specialty/work

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Person responsible for updating data

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