

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Efficacy of the Mucoadhesive Patch and Mouthwash Containing Zingiber Officinale Extract in the Management of Recurrent Aphthous Stomatitis

Protocol summary

Summary

Recurrent aphthous stomatitis (RAS) is the most common oral mucosal lesions in the general population. Various treatment modalities are being used; but no specific therapy proved to be definitive. Zingiber Officinale indicated to have anti-inflammatory properties in herbal medicine. Thus, this study aimed to evaluate the efficacy of Zingiber Officinale containing bioadhesive in treatment of aphthous ulcers. This is a double-blinded placebo randomized controlled trial study. Thirty patients enrolled in this study. Patients are randomly assigned in to two groups. All cases are evaluated during three aphthous periods for a minor aphthous stomatitis within the past 24h, confined to the lips and oral mucosa within each period. The clinical efficacy of the mucoadhesive patch or mouth wash on pain, inflammatory zone and ulcer's diameter in the test group will be compared with that of the base treatment and no treatment groups during 10 days of study. The patients will be asked to record the level of pain severity of the ulcers each day before meals and before bedtime through VAS (Visual Analogue Scale). The diameter of lesions and inflammatory zone will be measured and recorded in the profile of each case, by the examiner during the meetings at days 0, 1, 3, 5, 7 of the study. Eventually, to analyze the gathered data, SPSS ver. 18 will be employed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311101760N27**

Registration date: **2014-01-22, 1392/11/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-22, 1392/11/02

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2013-12-16, 1392/09/25

Expected recruitment end date

2014-03-06, 1392/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of the Mucoadhesive Patch and Mouthwash Containing Zingiber Officinale Extract in the Management of Recurrent Aphthous Stomatitis

Public title

The Efficacy of the Mucoadhesive Patch and Mouthwash Containing Zingiber Officinale Extract in the Management of Recurrent Aphthous Stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: minor pest record over the last 2 months. Exclusion criterion: major and several minor aphthous ulcers or sores in other areas of the mucosa, lips and cheeks.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

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**

The ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafroz Road

City

Babol

Postal code**Approval date**

2013-12-15, 1392/09/24

Ethics committee reference number

3461

Health conditions studied**1****Description of health condition studied**

Oral Mucositis

ICD-10 code

K12.3

ICD-10 code description

Oral mucositis

Primary outcomes**1****Description**

Minor aphthous ulcers

Timepoint

Seventh-day visit

Method of measurement

Clinical

Secondary outcomes**1****Description**

Lesion diameter

Timepoint

Zero, first, third, fifth and seventh days of referral

Method of measurement

clinical

2**Description**

Inflammatory halo size

Timepoint

Zero, first, third, fifth and seventh days of referral

Method of measurement

clinical

3**Description**

Pain

Timepoint

Zero , first, third, fifth and seventh days of referral

Method of measurement

Visual Analoge Scale(VAS)

Intervention groups**1****Description**

Intervention group: During three aphthous are studied. The first blow to fall markedly during registration per person and two other courses of treatment with a mouthwash (Ethanol, 96% ethanol extract of Zingiber with ml 500 gr 300. Ginger powder is prepared in the laboratory of Pharmacology, Babol University of Medical Sciences.) containing ginger (Dried extract prepared at a concentration of 4%) are studied. How to use sticky mucous and Mouthwash: Per day (after each meal and before bedtime) for 20 minutes. How mouthwash: Condition with a tablespoon or a mouthwash bottles kept in the wound for 30 seconds and then removed from the

mouth. It should be noted that the 7-day treatment until complete healing, patients are followed up and examined.

Category

Treatment - Drugs

2**Description**

Control(placebo): Based mouthwash (distilled water as a mouthwash base); Mucosal Adhesive Base (including gum (tragacanth), alcohol, sodium benzoate, and distilled water was prepared in the laboratory of Pharmacology, Babol University of Medical Sciences) for use sticky mucus and rinse in the day (after each meal and before bedtime) to for 20 minutes. How to use sticky mucous and Mouthwash: Per day (after each meal and before bedtime) for 20 minutes. How mouthwash: Condition with a tablespoon or a mouthwash bottles kept in the wound for 30 seconds and then removed from the mouth. It should be noted that the 7-day treatment until complete healing, patients are followed up and examined.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Department of Oral Medicine, Dental College of Babol

Full name of responsible person

Dr. Masoomah Haghpanah Aski

Street address

Dental College of Babol

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

Street address

Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Ganjafrooz Avenue

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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 and Technology, 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**

Dental College of Babol

Full name of responsible person

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Position

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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