Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 goups. 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 mucoadhessive 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. Masoomeh Haghpanah Aski

Street address

Dental College of Babol

City

Babol

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, Ganjafroz 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

Postgraduate Periodontics

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person
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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