

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

###### Phone

+98 11 3236 2282

###### Email address

zahra@mubabol.ac.ir

##### 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 Analogue 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**

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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, Ganjafroz Avenue

**City**

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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**

Dr. Masoomeh Haghpanah Aski

**Position**

Postgraduate Periodontics

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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*