

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation the effect of different myrtle extract concentrations on treatment of oral mucous aphthous ulcers.

#### Protocol summary

##### Summary

(1) Objectives: Studying the effect of various concentrations of Myrtels essence in treatment of oral mucus aphthous ulcers. (2) Design: 60 patients with oral mucus pathos who are divided randomly into two 30fold groups based on randomization numbers table are participated in this study. The approach of this study is double-blind approach and in trail phases 2 and 3. (3) Setting and conduct; First, the patients' specifications and also their aphthous ulcers size and their pain value are recorded. (4) Participants: The participants should not use other medicine before participating in the study and in case of consumption other medicine (drug) together with the advised solution will be excluded from the study. (5) Interventions: then a patients group is given 5% Myrtus solution and another group is given 2.5% Myrtus solution made in Kashan Barij Essence (Mirtex). Myrtus essence must be consumed by this way that the patients should pour 10 drops of the medicine on small cotton and put it for 20 seconds on aphthous ulcers 5 times per day this work shall be continued for 7 days. (6) Main outcome measures: After each consumption period, the patients' injury information included the injury size would be measured by putting a transparent paper (mm), injury irritation size can be measured by VAS.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015053020903N2**

Registration date: **2015-09-08, 1394/06/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-09-08, 1394/06/17

#### Registrant information

##### Name

zahra Roustaeizade Shouroki

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences and Health Services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3625 5884

##### Email address

dr.roustaei@ssu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Yazd University of Medical Sciences

#### Expected recruitment start date

2014-12-22, 1393/10/01

#### Expected recruitment end date

2015-07-23, 1394/05/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation the effect of different myrtle extract concentrations on treatment of oral mucous aphthous ulcers.

#### Public title

the effect of different myrtle extract on oral aphthous ulcers

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria :people who are diagnosed clinical oral

aphthous; do not have any systemic disease; infection with HIV; anemia; The patient's age must be between 20-40 years. Exclusion criteria: patients who are Challenge taking the drug; not present at the examination session .

#### **Age**

From **20 years** old to **40 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

Randomization According to Table of random numbers

## **Secondary Ids**

### 1

#### **Registry name**

#### **Secondary trial Id**

#### **Registration date**

2017-11-21, 1396/08/30

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Yazd University of Medical Sciences

##### **Street address**

Shahid sadoughi Boulvar, Yazd

##### **City**

Yazd

##### **Postal code**

#### **Approval date**

2015-01-20, 1393/10/30

#### **Ethics committee reference number**

223594

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Recurrent oral aphthae

#### **ICD-10 code**

K12.0

#### **ICD-10 code description**

Recurrent aphthous ulcer

## **Primary outcomes**

### 1

#### **Description**

size of lesion

#### **Timepoint**

before Intervention, one day after Intervention, seven days after Intervention.

#### **Method of measurement**

transparent millimetric paper

### 2

#### **Description**

pain and irritation

#### **Timepoint**

before Intervention, one day after Intervention, seven days after Intervention.

#### **Method of measurement**

visual analog scale(vas)

## **Secondary outcomes**

### 1

#### **Description**

-

#### **Timepoint**

-

#### **Method of measurement**

-

## **Intervention groups**

### 1

#### **Description**

using the 5% myrtle solution made by Baryj Essence Pharmaceutical Co. Kashan( Myrtex)The patients were instructed to apply 10 drops of 5% myrtle solution on a small piece of cotton and keep it on the lesion for 20 seconds and do it 5 times a day for 7 days

#### **Category**

Treatment - Drugs

### 2

#### **Description**

using the 2.5%( Diluted by ethanol) myrtle solution made by Baryj Essence Pharmaceutical Co. Kashan( Myrtex)The patients were instructed to apply 10 drops of 5% myrtle solution on a small piece of cotton and keep it on the lesion for 20 seconds and do it 5 times a day for 7 days

#### **Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

College Dentistry of Yazd

**Full name of responsible person**

Ehsan Babaei Zarch

**Street address**

College Dentistry of Yazd.Dahe Fajr Boulevard.Yazd

**City**

Yazd

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research,Yazd University of  
Medical Sciences

**Full name of responsible person**

Fatemeh Ghezry

**Street address**

College Dentistry of Yazd.Dahe Fajr Boulevard.Yazd

**City**

Yazd

**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,Yazd 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**

Shahid Sadoughi University of Medical Sciences and  
Health Services

**Full name of responsible person**

Zahra Roustaeizadeh

**Position**

Assistant Professor of oral medicine

**Other areas of specialty/work**

**Street address**

College Dentistry of Yazd.Dahe Fajr Boulevard.Yazd

**City**

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esi.ebz@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences and  
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**Full name of responsible person**

zahra roustaei zadeh

**Position**

Assistant Professor of oral medicine

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## Person responsible for updating data

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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*