

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of therapeutic effect of pro biotic medication on oral recurrent aphtus ulcers

Protocol summary

Study aim

Determination of the effect of probiotic medication produced by Lactobacillus reuteri on minor oral aphtus ulcers

Design

Clinical trials with parallel groups include the control group and the intervention group. By selecting 40 eligible patients, 20 patients in the control group and 20 patients in the intervention group will be randomly assigned to the cluster randomized. This study was designed in Phase 2-3 clinical trials.

Settings and conduct

This study was designed to investigate the effects of alternative therapies for oral pest infections. The plan will be conducted at Shiraz University of Medical Sciences.

Participants/Inclusion and exclusion criteria

inclusion criteria : patients with oral aphtus ulcers between 15 -80 years old. patients with oral aphtus ulcers without any systemic medication during last 6 months. patients with one to three oral aphtus ulcers in their mouths Patients with oral lesions that do not have a day off at the beginning of the lesion (the lesion is on the first day of appearance) Patients with oral lesions that do not have a history of rheumatologic disease, GI disease, renal disease, and iron deficiency anemia. exclusion criteria : Patients with oral aphtus lesions that have had a lesion more than one day. pregnant patients Patients with diffuse oral lesions and more than 3 concurrent lesions Patients who do not have the opportunity to travel for frequent or repeated examinations.

Intervention groups

In the control group, oral lesions relief by standard analgesic oral mouth rinse and the intervention group use the pro biotic medication is used as a lactobacillus strain (lactobacillus reuteri) in gel form.

Main outcome variables

The size of the lesions in millimeters Severity of burning and pain based on visual analogue score (VAS) (score

between 0-10) Duration of recovery in terms of number of days

General information

Reason for update

Acronym

RAS or recurrent aphtus stomatitis

IRCT registration information

IRCT registration number: **IRCT20110428006322N2**

Registration date: **2019-10-17, 1398/07/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-17, 1398/07/25**

Update count: **0**

Registration date

2019-10-17, 1398/07/25

Registrant information

Name

Mostafa Rezaee

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1635 6681

Email address

rezaim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-11-06, 1398/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effect of pro biotic medication on oral recurrent aphthous ulcers

Public title

probiotic on oral aphthous ulcers

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with oral aphthous ulcers between 15 -80 years old. patients with oral aphthous ulcers without any systemic medication during last 6 months. patients with one to three oral aphthous ulcers in their mouths Patients with oral lesions that do not have a day off at the beginning of the lesion (the lesion is on the first day of appearance) Patients with oral lesions that do not have a history of rheumatologic disease, GI disease, renal disease, and iron deficiency anemia.

Exclusion criteria:

Patients with oral aphthous lesions that have had a lesion more than one day. pregnant patients Patients with diffuse oral lesions and more than 3 concurrent lesions Patients who do not have the opportunity to travel for frequent or repeated examinations.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **20**

In the control group, oral lesions relief by standard analgesic oral mouth rinse and the intervention group use the pro biotic medication is used as a lactobacillus strain (lactobacillus reuteri) in gel form.

Randomization (investigator's opinion)

Randomized

Randomization description

clustered block randomization ,To ensure that exactly the same number of participants were placed in the intervention and control groups at regular intervals but at equal intervals, we considered the size of each block as 10 individuals. For example, one type of treatment or intervention will be occurred to the first block and the other intervention or treatment to the second block and again the same cycle until the last block. In this study we have 3 to blocks that include 10 individuals.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients and assessors or examiners are not aware of the type of treatment provided. The patient receives treatment from the beginning, which is unclear whether the treatment is new or the standard treatment (on the other hand) and the examiner does not need to know what medicine the patient has used, it only records the information.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Ghasr-e-Dasht St., Corner of Mehr St., Shiraz Dental School

City

Shiraz

Province

Fars

Postal code

1587871956

Approval date

2019-09-08, 1398/06/17

Ethics committee reference number

IR.SUMS.DENTAL.REC.1398.103

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

oral recurrent aphthous ulcer

ICD-10 code

K12

ICD-10 code description

Stomatitis and related lesions

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

The size of the lesions in millimeters

Timepoint

determination at 1,3,5 and 7 days

Method of measurement

size determination by ruler

2

Description

Severity of burning and pain based on visual analogue score (VAS) (score between 0-10)

Timepoint

determination at 1,3,5 and 7 days

Method of measurement

Evaluation by VAS method and numerical expression of pain and burning intensity

3

Description

Duration of recovery in terms of number of days

Timepoint

daily check for seven days

Method of measurement

Improvement of clinical symptoms, absence of oral lesions and complete relief of burning and pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment with probiotic product or probiotic products from *Lactobacillus routeri* is administered in a gel-sol form, which patients put in the mouth on the lesion and should not swallow the drug. The drug is formulated in the Biotechnology and Pharmacotechnics department of Shiraz Pharmacy School and is not a mass production or drug owned by a particular pharmaceutical company. The product should be applied 3 times daily to the oral lesion for at least 2-3 minutes for 10 days. The product is based on the drug protocols and approved drug standards at the School of Pharmacy and its route of manufacture is part of the process of this study. The content of this drug is merely a probiotic product, and the drug is in the form of a gel-sol form, a relatively diluted state that makes it easier for the patient to use the drug. Use of probiotic products in the pharmaceutical process Considering that they are used in many nutritional supplement products and offer immune-enhancing or immune-enhancing roles, they are considered safe products in most pharmaceutical supplements.

Category

Treatment - Drugs

2

Description

Control group: receive standard analgesic treatment for treatment (Standard compound oral mouthwash with analgesic effect) , For the control group patients receive conventional topical analgesics, including Diphenhydramine syrup + Aluminum Mg suspension (both manufactured by Iran Pakhsh Pharmacopoeia Iran)

with a ratio of one to one, and a similar container is given to the intervention group. The drug is prescribed 3 times a day for 10 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental faculty of Shiraz University of Medical Sciences

Full name of responsible person

Mostafa Rezaee

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr . Yonnes Ghasemi

Street address

Ghasr-e-Dasht St., Corner of Mehr St., Shiraz Dental School

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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

Shiraz University of Medical Sciences

Proportion provided by this source

80

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mostafa Rezaee

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

In this study, due to the confidentiality of the individual data of the participants, only the executive protocol, data analysis method, and general plan information are shared in the article.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

this only available for people working in academic institutions

Under which criteria data/document could be used

only for research propose

From where data/document is obtainable

email address

What processes are involved for a request to access data/document

Send an email to the planner and contact person to receive the required information. In the absence of the

problem, the information required will be less than 2 weeks

Comments
no