Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 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 returri) 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

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Iran (Islamic Republic of)

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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 aphtus ulcers

Public title
probiotic on oral aphtus ulcers
Purpose
Treatment
Inclusion/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.
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 returri) 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
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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 aphtus 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
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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
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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