Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Mumijo (Shilajit) mouthwash on pain and healing of oral lichen planus

Protocol summary

Study aim
This study aims to prepare mouthwash form of Shilajit and its efficacy evaluation

Design
Clinical trial phase 1-2 with a control group, with parallel groups, randomized trial with blinded outcome assessment

Settings and conduct
This study will be done on patients with oral lichen planus lesions who will be referred to the Oral and Maxillofacial Disease Department of Shiraz Dental School. In one group, the Shilajit mouthwash, and Triamcinolone mouthwash will be prescribed for the other group. The assessor of outcomes will be blinded to the type of prescribed medication.

Participants/Inclusion and exclusion criteria
Inclusion criteria: the patients with atrophic or erosive oral lichen planus; the patients with histopathology and clinically conformed lichen planus; the patients who will be referred to Oral and Maxillofacial Disease Department of Shiraz Dental School. Exclusion criteria: the patients with a history of other inflammatory diseases; the patients with a history of malignancies or even dysplastic lesions; the patients who have received treatment for oral lichen planus lesions since a previous month; pregnant women.

Intervention groups
The patient in the intervention group will be prescribed Triamcinolone mouthwash 3 times a day for a month. For each time, 10 ml of this mouthwash will be gargled. They will be prescribed Shilajit mouthwash either. The Shilajit mouthwash will be used topically three times a day for a month (10 ml) it will be gargled for 4 minutes and the participants should not eat or drink for 30 minutes after using the mouthwash. In the control group, patients will be prescribed Triamcinolone mouthwash 3 times a day for a month. For each time, 10 ml of this mouthwash will be gargled. All the patients in both groups will be prescribed to use nystatin mouthwash for candida infection control.

Main outcome variables
pain; healing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120101008585N9**
Registration date: **2021-10-29, 1400/08/07**
Registration timing: **prospective**

Last update: **2021-10-29, 1400/08/07**
Update count: **0**

Registration date
2021-10-29, 1400/08/07

Registrant information

Name
Fatemeh Lavaee

Name of organization / entity
Shiraz Dental School

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Mumijo (Shilajit) mouthwash on pain and healing of oral lichen planus

Public title
Evaluation of the effect of Shilajit on oral lichen planus lesions
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patients with atrophic or erosive oral lichen planus The patients with histopathology and clinically conformed lichen planus The patients who will be referred to Oral and Maxillofacial Disease Department of Shiraz Dental School
Exclusion criteria:
The patients with history of other inflammatory diseases The patients with history of malignancies or even dysplastic lesions The patients who have received treatment for oral lichen planus lesions since a previous month pregnant women
Age
From **18 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Each block with 4 allocations, consisting of 2 allocations for intervention and 2 for the control group will be considered. Six possible sequences of treatment allocation in each block will be listed and each one will be written on a card. For each time, a block will be selected and the sequence of treatment will be registered until the treatment allocations become completed for all 30 participants (8 blocks). The randomization is performed by a methodologist. Allocation concealment is done by the main researcher. On every 30 cards, a sequence will be written and sealed. Pockets will be put in a box. A pocket will be allocated for each participant based on the order of enrollment.
Blinding (investigator's opinion)
Single blinded
Blinding description
The outcome assessor will be blinded to the type of prescribed medication.
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
Shiraz University of Medical Sciences, Namazi square, Zand street, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7186781559
Approval date
2020-07-26, 1399/05/05
Ethics committee reference number
IR.SUMS.DENTAL.REC.1400.011

Health conditions studied

1

Description of health condition studied
Lichen planus
ICD-10 code
L43
ICD-10 code description
Lichen planus

Primary outcomes

1

Description
Pain
Timepoint
Week: 1, 2 , 4, and 8
Method of measurement
Visual analogue scale

2

Description
Lesion size
Timepoint
Week: 1, 2 , 4, and 8
Method of measurement
Scaled tongue blade (mm)

3

Description
Clinical presentation or inflammation
Timepoint
Week: 1, 2 , 4, and 8
Method of measurement
Thongprasom sign scoring

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the patient in the intervention group will be prescribed Triamcinolone mouthwash (Raha Daru-Isfahan) 3 times a day for a month in order not to be derivate from routine treatment. This mouthwash will be prepared by mixing 10 vials of an amp. Triamcinolone 40 mg/ml in 200 cc boiled cooled water. For each time, 10 ml of this mouthwash will be gargled. They will be prescribed Shilajit mouthwash either. The Shilajit mouthwash will be used topically three times a day for a month (10 ml) it will be gargled for 4 minutes and the participants should not eat or drink for 30 minutes after using the mouthwash. After each meal, it will be prescribed. Similar to the control group, nystatin mouthwash will be prescribed for them for the candida infection control.
Category
Treatment - Drugs

2

Description
Control group: in the control group, patients will be prescribed Triamcinolone mouthwash (Raha Daru-Isfahan) 3 times a day for a month. This mouthwash will be prepared by mixing 10 vials of an amp. Triamcinolone 40 mg/ml in 200 cc boiled cooled water. For each time, 10 ml of this mouthwash will be gargled. All the patients same as the intervention group will be prescribed to use nystatin mouthwash for candida infection control.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Recruitment center School of Dentistry, Shiraz University of Medical Sciences
Full name of responsible person
Dr. Fateme Lavaee
Street address
Shiraz Dental School, Ghasrdasht street, Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Abbas Rezaianzadeh
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rezaiana@sums.ac.ir
Grant name
Grant code / Reference number
20795
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
100
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
Fatemeh Lavaee
Position
Assistant Professor of Oral and Maxillofacial Medicine Department

Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shiraz School of Dentistry, Ghasrdasht street, Shiraz, Iran
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Person responsible for scientific inquiries

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Position
Assistant Professor of Oral and Maxillofacial Medicine Department
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
Yes - There is a plan to make this available
Title and more details about the data/document
All collected data will be shared after the deidentification of participants.
When the data will become available and for how long
6 months after publication data will become available.
To whom data/document is available
The researchers in academic institutions
Under which criteria data/document could be used
The researchers in academic institutions.
From where data/document is obtainable
The researchers in academic institutions can email the responsible persons and request information.
What processes are involved for a request to access data/document
The researchers in academic institutions can email the responsible persons and request information.
Comments