Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of platelet-rich plasma on pain and size of oral lichen planus

Protocol summary

Study aim

- Determination the effect of platelet-rich plasma injections and triadent oral paste on the VAS and Thongpressam scale of patients with oral lichen planus on day 0, 7,14, 30, 60

Design

Clinical trial phase 1-2 with control group, with parallel groups, randomized trial with double blinded outcome assessment on 15 patients. block randomization will be used.

Settings and conduct

This study will be done on patients with oral lichen planus lesions who will be referred to Oral and Maxillofacial Disease Department of Shiraz Dental School. In one side of intervention group, the paltelet rich plasma and triadent will be prescribed and for control side just triadent. The assessor of outcomes and statistical analysor will be blinded to the type of prescribed medication.

Participants/Inclusion and exclusion criteria

Inclusion: The patients with histopathology and clinically conformed atrophic or erosive oral lichen planus
Exclusion: The patients with history of other inflammatory diseases, malignancies or even dysplastic lesions

Intervention groups

Intervention group: The prepared PRP will be injected around the lesion and intra lesion with anesthesia by insulin syringe twice (once every week) during first two weeks beside twice in a day use of triadent oral paste 0.1% (Raha Pharmaceutical company- Iran) .The VAS and thongpressom scale will assed the pain, size (days 0, 7, 14, 30, 60). Control group: The patient with two-sided OLP will be under routine treatment during the study. Both sides OLP lesions will be treated by triadent oral paste 0.1% (Raha Pharmaceutical company- Iran) twice in a day. The lesion on control side will only receive triadent. The VAS and thongpressom scale will assed the pain, size on days 0, 7, 14, 30, 60.

Main outcome variables

Pain, size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120101008585N10**
Registration date: **2021-11-10, 1400/08/19**
Registration timing: **prospective**

Last update: **2021-11-10, 1400/08/19**
Update count: **0**

Registration date

2021-11-10, 1400/08/19

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

2021-12-21, 1400/09/30

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of platelet-rich plasma on pain and size of oral lichen planus

Public title
The effect of platelet-rich plasma on oral lichen planus

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 pregnant women The patients with history of malignancies or even dysplastic lesionsThe 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

- Outcome assessor
- Data analyser

Sample size
Target sample size: **15**
More than 1 sample in each individual
Number of samples in each individual: **2**
The patients with two-sided atrophic or erosive oral lichen planus, two different intervention will be done on lesions of each side

Randomization (investigator's opinion)
Randomized

Randomization description
Each block with 4 allocations, consisting 2 allocation for intervention and 2 for control group will be considered. Six possible sequence of treatment allocation in each block will be listed and each one will be written on a card. 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 was performed by a methodologist. Allocation concealment will be done by the main researcher. On each 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 order of enrollment.

Blinding (investigator's opinion)
Double blinded

Blinding description
The outcome assessor, patient and data analyzer 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
2020-09-02, 1399/06/12

Ethics committee reference number
IR.SUMS.REC.1399.734

Health conditions studied

1

Description of health condition studied
Oral lichen planus

ICD-10 code
L43

ICD-10 code description
Lichen planus

Primary outcomes

1

Description
Pain

Timepoint
Days 0, 14, 30, 60

Method of measurement
Visual analogue scale

2

Description
Size

Timepoint
Days 0, 14, 30, 60

Method of measurement
Scaled tongue blade(mm)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The prepared PRP will be injected around the lesion and intra lesion with anesthesia by insulin syringe. The injections will be performed twice (once every week) during first two weeks (days 0, 7, 14, 30, 60). Follow up sessions are weekly until the end of the second month (days 0, 7, 14, 30, 60). The VAS and thongpressom scale will assed the pain, size. The patient with two-sided OLP will be under routine treatment during the study. Both sides OLP lesions will be treated by triadent oral paste 0.1% (Raha Pharmaceutical company- Iran) twice in a day. The lesion on intervention side will receive PRP in addition to triadent. All participants will also be prescribed for 40 drops of Nystatin oral drop 100000U (Emad Darman Pars- Iran) twice in a day.

Category
Treatment - Drugs

2

Description
Control group: The patient with two-sided OLP will be under routine treatment during the study. Both sides OLP lesions will be treated by triadent oral paste 0.1% (Raha Pharmaceutical company- Iran) twice in a day. The lesion on control side will only receive triadent. All participants will also be prescribed for 40 drops of Nystatin oral drop 100000U (Emad Darman Pars- Iran) twice in a day.The VAS and thongpressom scale will assed the pain, size on days 0, 7, 14, 30, 60.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Dentistry, Shiraz University of Medical Sciences

Full name of responsible person
Fatemeh Lavaee

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number
98-01-21-21242

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
Iran University of Medical Sciences

Full name of responsible person
Shiraz University of Medical Sciences

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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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 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 responsible person and request information
What processes are involved for a request to access data/document
The researchers in academic institutions can email responsible person and request information
Comments