# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

06 Jun 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)
**Phone**
+98 71 1631 9309
**Email address**
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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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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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Shiraz university of Medical Sciences, Zand street, Iran

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rezaeianzadeha@sums.ac.ir

**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 scientific inquiries

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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**