

# Management of oral lichen planus with triamcinolone acetonide and injectable platelet-rich fibrin

<b>Submission date</b> 18/06/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 09/07/2021	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 09/07/2021	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Oral lichen planus is an inflammatory condition that affects the mucous membranes inside the mouth. This study aims to compare injectable platelet-rich fibrin and triamcinolone acetonide injections for the treatment of oral lichen planus.

### Who can participate?

Patients over 18 years old with bilateral oral lichen planus

### What does the study involve?

Participants are randomised by coin toss to decide which side of their mouth is to be treated with injectable platelet-rich fibrin and which is to be treated with triamcinolone acetonide. After local anaesthesia, the treatment is injected in several sites in the mouth once a week for 4 weeks. During the treatment, participants are assessed at weeks 0, 1, 2, 3, 4 and then once a month for 3 months.

### What are the possible benefits and risks of participating?

The results of the study may lead to an effective and efficient treatment for oral lichen planus with few or no side effects.

### When is the study starting and how long is it expected to run for?

April 2019 to October 2021

### Where is the study run from?

Damascus University (Syria)

### Who is funding the study?

Damascus University (Syria)

Who is the main contact?  
Dr Noor Abdulrahman Alhallak  
nooralhallak93@gmail.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Noor Alhallak

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## Additional identifiers

**Protocol serial number**  
MS3030

## Study information

**Scientific Title**  
Management of oral lichen planus lesions using intralesional platelet-rich fibrin and triamcinolone acetonide injection

**Study objectives**  
The researchers are trying to test the efficacy of injectable platelet-rich fibrin and comparing it to triamcinolone acetonide injection in the treatment of oral lichen planus.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Approved 26/08/2019, Damascus University Rector (Baramkeh, Damascus, Syria; +966 (0)55 506 3806; email: not available), ref: MS3030

**Study design**  
Split-mouth randomized controlled trial

**Primary study design**  
Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Bilateral oral lichen planus lesions

**Interventions**

This study is a split-mouth randomised clinical trial. Participants are randomised by coin toss to decide which side of their mouth is to be treated by injectable platelet-rich fibrin and which is to be treated by triamcinolone acetonide (40 mg/ml). After local anesthesia, the injection is placed in several sites directly into the subepithelial connective tissue just underlying the lesion adjacent to normal mucosa, once a week for 4 weeks. During the treatment, participants are assessed at weeks 0, 1, 2, 3, 4 and then once a month for 3 months.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Injectable platelet-rich fibrin, triamcinolone acetonide

**Primary outcome(s)**

Pain measured using a Visual Analog Scale (VAS) once a week during treatment for 4 weeks

**Key secondary outcome(s)**

1. Clinical presentation of oral lichen planus measured using the REU scoring system at 1, 2, 3 and 4 weeks
2. Treatment response: surface areas of erythema and ulceration measured with a sterile flexible periodontal scale probe at 1, 2, 3 and 4 weeks
3. Recurrence rate measured by clinical examination at the end of treatment (day 30)
4. Quality of life measured using OHIP- 14 before treatment and at the end of treatment (day 30)

**Completion date**

01/10/2021

**Eligibility****Key inclusion criteria**

Patients diagnosed with oral lichen planus lesions

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Total final enrolment**

12

**Key exclusion criteria**

1. Patients with systemic disease
2. A history of topical therapy for oral lichen planus in the last 2 weeks or systemic treatment for oral lichen planus in the last 3 months
3. Pregnancy or lactation
4. Patients who had taken immunodepressant drugs the past 3 months

**Date of first enrolment**

15/09/2019

**Date of final enrolment**

01/07/2021

**Locations****Countries of recruitment**

Syria

**Study participating centre****Damascus University**

Department of Oral Medicine

Mazzah High Way

Damascus

Syria

0096311

**Sponsor information****Organisation**

Damascus University

**ROR**

<https://ror.org/03m098d13>

**Funder(s)****Funder type**

University/education

## Funder Name

Damascus University

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Noor Abdulrahman Alhallak (nooralhallak93@gmail.com).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			09/07/2021	No	Yes
<a href="#">Protocol file</a>			09/07/2021	No	No