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

Submission date	Recruitment status	[_] Prospectively registered
18/06/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/07/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/07/2021	Skin and Connective Tissue Diseases	[_] 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 Abdualrahman Alhallak
nooralhallak93@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Noor Alhallak

Contact details
Mazzeh
Damascus
Syria
0096311
+963 (0)934459512
noor7.alhallak@damascusuniversity.edu.sy

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

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

Secondary outcome measures
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)

Overall study start date
23/04/2019

Completion date
01/10/2021

Eligibility

Key inclusion criteria
Patients diagnosed with oral lichen planus lesions

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
12

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

Sponsor details
Damascus University Rector
Baramkeh
Damascus
Syria
0096311
+963 (0)1133923192
info@damascusuniversity.edu.sy

Sponsor type
University/education

Website
http://damasuniv.edu.sy/

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Results and Publications

Publication and dissemination plan

After finishing the follow-up procedure and writing the article, the researchers are planning to publish (with all results, statistical analysis and some photos) in Damascus University's journal, and many other international journals.

Intention to publish date
01/09/2022

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 Abdualrahman Alhallak (nooralhallak93@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			09/07/2021	No	Yes
Protocol file			09/07/2021	No	No