

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The evaluation of oral vitamin D on improvement of patients with oral erosive-atrophic lichen planus: Double blind randomized clinical trial

Protocol summary

Study aim

Lichen planus is a chronic Immunological mucocutaneous disease which cytokines such as TGF- β , IFN- α , TNF- α and IL-6 play a role in its pathogenesis. According to the high prevalence of vitamin D deficiency in Iran (nearly 80 percent) and since the effect of vitamin D on the immune system and many of these cytokines was proved, this study is aimed at investigating effect of vitamin D in patients with Oral Lichen Planus (OLP) with Vit D deficiency or insufficiency.

Design

A randomized, double blinded, controlled trial (phase III) for 28 patients has been designed. Seal envelope will be used to randomize.

Settings and conduct

This study is designed based on role of cytokines in pathogenesis of oral lichen planus and effect of vitamin D on cytokines and vitamin D deficiency. This study will be done on oral lichen planus patients referred to Mashhad Dental School. Participants and care providers and assessing outcomes and statistician are blinded to type of drug because drugs are placed in similar seal envelope packs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with erosive-atrophic oral lichen planus, who have not used any systemic or topical drug for the treatment of lichen planus over the past 2 weeks and they have not used any vitamin supplement, in the past 3 months. They have vitamin D deficiency or insufficiency (25 (OH) D <30 mg / dl).

Exclusion criteria: Dysplasia or ichenoid reaction, calcium levels above 10 mg / dl, phosphorus less than 2.5 mg / dl, pregnancy, metabolic bone diseases such as: osteomalacia and primary hyperparathyroidism, history of severe renal-hepatic dysfunction, allergy to vitamin D supplements, usage of barbiturates and phenytoin, granulomatous diseases, malabsorption or chronic pancreatitis.

Intervention groups

Pearl Vit D (A) and placebo (B) are made in similar capsules by pharmacist. Capsules are placed in some paper packs. Intervention group will use pearl Vit D and control group will use placebo, one pearl every week for 8 weeks.

Main outcome variables

Burning and pain, type and severity of lesions, levels of vitamin D and cytokines

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171017036835N2**

Registration date: **2018-03-08, 1396/12/17**

Registration timing: **prospective**

Last update: **2018-03-08, 1396/12/17**

Update count: **0**

Registration date

2018-03-08, 1396/12/17

Registrant information

Name

Zohreh Dalirsani

Name of organization / entity

Oral and maxillofacial department, Mashhad Dental School

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

vice chancellor of research, MUMS (Mashhad University of Medical Sciences)

Expected recruitment start date

2018-03-23, 1397/01/03

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of oral vitamin D on improvement of patients with oral erosive-atrophic lichen planus: Double blind randomized clinical trial

Public title

The effect of vitamin D on oral lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Patients with erosive-atrophic oral lichen planus with confirmation of clinical diagnosis and histopathology confirmation. 2. Patients have not used any systemic or topical drug for the treatment of lichen planus over the past 2 weeks. 3. In the past 3 months, they have not used any vitamin supplements. 4. Patients aged 18-80 years old were considered. 5. People with vitamin D deficiency or insufficiency (25 (OH) D <30 mg / dl). 6. Patients with grade 2 to 5 Thongprosam criteria will enroll in this study.

Exclusion criteria:

1. People who have been diagnosed with , mild to severe dysplasia. 2. Calcium levels above 10 mg / dl, phosphorus less than 2.5 mg / dl (rejection of hyperparathyroidism) 3. lichenoid reaction. 4. Patients who do not have the necessary co-operation or attending the control sessions. 5. Pregnant women 6. Metabolic bone diseases such as: osteomalacia and primary hyperparathyroidism (with endocrinologist confirmation) 7. Patient with a history of severe renal-hepatic dysfunction 8. Chronic inflammatory disease in addition to lichen planus 9. If you have a history of being allergic to vitamin D supplements (itching, inflammation or redness in the skin and cramps, then using the supplementation of this vitamin) 10. Patients who use barbiturates and phenytoin. 11. Patients with granulomatous diseases, including sarcoidosis 12. History of malabsorption or chronic pancreatitis

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

seal envelope

Blinding (investigator's opinion)

Double blinded

Blinding description

1. pearl Vit D (A) and placebo (B) are made in similar capsules by pharmacologist. 2. capsules are placed in some paper packs. 3. seal envelope will be used to randomize. 4. Participants and care providers and assessing outcomes and statistician are blinded to type of drug.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mashhad University of Medical Sciences- Research Ethics Committee

Street address

Vice chancellor of research, MUMS (Mashhad University of Medical Sciences)

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2015-09-09, 1394/06/18

Ethics committee reference number

IR.MUMS.SD.REC.1394.15

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

Burning and pain

Timepoint

every 2 week for 2 months

Method of measurement

visual analogue scale

2

Description

size and severity of lesion

Timepoint

every 2 week for 2 months

Method of measurement

thongprasom

Secondary outcomes

1

Description

cytokines TNF- α and IL-6

Timepoint

before treatment and 2 month later

Method of measurement

ELISA

Intervention groups

1

Description

After laboratory tests, for intervention patients(13 patients), 2-3 times a day, a dexamethasone mouthwash and nystatin mouthwash (Jaber ebne Hayan Company) will be prescribed, for 8 weeks. Additionally, vitamin D capsules 50000IU (manufactured by Dana Pharmaceutical Company) will be prescribed, one pearl every week, for 8 weeks. Also, the patients will be evaluated according to pain and burning and type and severity of the lesions . Cytokines and Vit D levels will be assessed before and two months after treatment.

Category

Treatment - Drugs

2

Description

After laboratory tests, for control group,(15 patients), 2-3 times a day, a dexamethasone mouthwash and nystatin mouthwash (Jaber ebne Hayan Company) will be prescribed, for 8 weeks. Additionally, placebo capsules filled with lactose and in the same weight of vitamin D capsuls will be prescribed, one capsule every week, for 8 weeks. Also, the patients will be evaluated according to pain and burning and type and severity of the lesions . Cytokines and Vit D levels will be assessed before and two months after treatment.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and maxillofacial Diseases Department of Mashhad Dental School

Full name of responsible person

Zahra Delavarian

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Oral and maxillofacial Diseases Department of Mashhad Dental School

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Mashhad University of Medical Sciences, Daneshgah St.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Asieh Rahimi

Position

Project colleague

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Zahra Delavarian

Position

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Latest degree

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Position

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Latest degree

Specialist

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some data including demographic properties, signs and symptoms, Vit D and cytokines levels.

When the data will become available and for how long

two months after article publication.

To whom data/document is available

academic researchers

Under which criteria data/document could be used

It is permitted to use the data in other studies with reference.

From where data/document is obtainable

Dr. Asieh Rahimi email: dr.rahimi.79@gmail.com

What processes are involved for a request to access data/document

sending email to authors. the authors will send data via email during 4 weeks.

Comments

