Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Study aim

Lichen planus is a chronic Immunological mucocutaneouys 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 parthenogenesis 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 pharmacologist. 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

Country

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 erosiver-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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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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Professor of oral and maxillofacial medicine
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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
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