

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Evaluation the treatment effect of vitamin D deficiency on the improvement of dry eye

#### Protocol summary

##### Study aim

Evaluation the treatment effect of vitamin D deficiency on the improvement of dry eye

##### Design

Randomized clinical trial with parallel groups in 100 patients

##### Settings and conduct

Among patients referred to Khatam Alanbia hospital, 100 cases who were suffering simultaneously from Vit D deficiency (serum Vit D level below 20 ng/ml) and dry eye which is defined by schirmer, tear breakup time and tear lab test is selected. These patients then was randomly categorized in to two groups, case and control group. The case group is treated with 50000 units Vit D weekly until the serum Vit D level become normal and reaches levels more than 20 ng/ml. Both groups get similar dry eye treatment. After treating Vit D deficiency in case control, dry eye assessment is done again and the results will be compare between two groups in order to evaluate the vit d deficiency on dry eye.

##### Participants/Inclusion and exclusion criteria

Inclusion criterion: dry eye and vitamin D deficiency.  
exclusion criteria: any history of eye surgery or disease(except dry eye); intake of vitamin D.

##### Intervention groups

Intervention group: treatment of vitamin D deficiency with pearl 50000 u vitamin D per week until 8 weeks.  
Control group: routine treatment of dry eye with artificial tear drop.

##### Main outcome variables

Schirmer test; tear breakup time test; tear osmolarity; serum level of vitamin D

#### General information

##### Reason for update

Correction of the mistake made in the section on randomization in the general information section, considering that in the abstract section, the type of

randomized clinical trial study was previously mentioned correctly.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190407043184N1**

Registration date: **2019-11-23, 1398/09/02**

Registration timing: **prospective**

Last update: **2020-12-19, 1399/09/29**

Update count: **1**

##### Registration date

2019-11-23, 1398/09/02

##### Registrant information

###### Name

Ehsan Arjmand askari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3728 1401

###### Email address

arjmandae941@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-26, 1398/09/05

##### Expected recruitment end date

2020-01-25, 1398/11/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the treatment effect of vitamin D deficiency

on the improvement of dry eye

## Public title

Evaluation the treatment effect of vitamin D deficiency on the improvement of dry eye

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Dry eye and vitamin D deficiency

### Exclusion criteria:

Any history of eye surgery or disease(except dry eye)  
Intake of vitamin D

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random allocation We poured 100 balls containing the names of the people who met the inclusion criteria into a lottery tank and the first 50 balls that came out as the intervention group and the remaining 50 balls as the control group entered in to study.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of mashhad University of Medical Sciences

##### Street address

Aboutaleb cross; Khatam ol Anbiae hospital

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9196643646

#### Approval date

2017-08-09, 1396/05/18

## Ethics committee reference number

lr.mums.fm.rec.1396.254

## Health conditions studied

### 1

#### Description of health condition studied

Dry eye syndrome

#### ICD-10 code

H04.1

#### ICD-10 code description

Dry eye syndrome

## Primary outcomes

### 1

#### Description

Schirmer test

#### Timepoint

Measurement of schirmer test at baseline and 8 weeks after the intervention

#### Method of measurement

With schirmer paper

### 2

#### Description

Tear breakup time test

#### Timepoint

Measurement of Tear breakup time test at baseline and 8 weeks after the intervention

#### Method of measurement

With fluorescein paper and slit lamp and no anesthetics

### 3

#### Description

Tear osmolarity

#### Timepoint

Measurement of tear osmolarity at baseline and 8 weeks after the intervention

#### Method of measurement

With Tearlab osmolarity system

### 4

#### Description

Serum level of vitamin D

#### Timepoint

Measurement of serum level of vitamin D at baseline and 8 weeks after the intervention

#### Method of measurement

Vitamin D blood test

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: treatment of vitamin D deficiency with pearl 50000 u vitamin D per week until 8 weeks

### Category

Treatment - Drugs

2

### Description

Control group: routine treatment of dry eye with artificial tear drop

### Category

N/A

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Khatam al Anbia hospital

#### Full name of responsible person

Ehsan Arjmand Askari

#### Street address

Aboutaleb cross; Khatam al Anbia hospital

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9196643646

#### Phone

+98 51 3728 1401

#### Email

Arjmandae941@mums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Saeid Eslami

#### Street address

Ghoreyshi building; Daneshgah ave.

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9195965919

#### Phone

+98 51 3845 2474

#### Email

ramresearch@mums.ac.ir

#### 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

Ehsan Arjmand Askari

#### Position

Resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Ophthalmology

#### Street address

Abutaleb cross; Khatam al Anbia hospital

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9196643646

#### Phone

+98 51 3728 1401

#### Fax

#### Email

arjmandae941@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Ehsan Arjmand Askari

#### Position

Resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

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arjmandae941@mums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Ehsan Arjmand Askari  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
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**Email**  
arjmandae941@mums.ac.ir

## 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

Any detail going to published

### When the data will become available and for how long

6 months after validity

### To whom data/document is available

Any scientific and collegiate institutions

### Under which criteria data/document could be used

Any analysis allowed

### From where data/document is obtainable

Arjmandae941@mums.ac.ir

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

About 1 month after request with email

### Comments