

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 were randomly categorized into two groups, case and control group. The case group is treated with 50000 units Vit D weekly until the serum Vit D level becomes 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 compared 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

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

Method of measurement

With schirmer paper

2

Description

Tear breakup time test

Timepoint

Measurment 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

Measurment 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

Measurment 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

Ophthalmology

Street address

Abutaleb cross; Khatamol Anbia hospital

City

Mashhad
Province
Razavi Khorasan
Postal code
9196643646
Phone
+98 51 3728 1401
Fax
Email
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
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

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