

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Prevalence of dry eye in vitamin D deficiency patients that referred to the Jahrom Honary Clinic and the effect of vitamin D treatment on the dry eye parameters in 1394-1395

Protocol summary

Study aim

Investigating the therapeutic role of vitamin D on dry eye parameters

Design

Randomized Clinical Trial without control group, Not blind Phase 2 was performed on 50 patients.

Settings and conduct

This study is based on the high prevalence of these two disorders in the community and with the aim of investigating the prevalence and relationship between dry eye and serum deficiency 25OHD and also examining the effect of vitamin D treatment on dry eye parameters, on 90 patients referred to endocrinology and ophthalmology clinic Jahrom medicine, which is also deficient in serum 25OHD and dry eye, should be performed.

Participants/Inclusion and exclusion criteria

Conditions for entering the study: Patients referring to the endocrinology clinic of Jahrom University of Medical Sciences with abnormal serum levels of 25OHD
Conditions for not entering the study: Patients with Ss (Sjogren's Syndrome) or with a history of other systemic rheumatic diseases, thyroid disease, vitamin A deficiency, glucocorticoid medications, antidepressants, contraceptives, estrogen, people with vitamin B12 deficiency, disorders and wearing contact lenses eye level, type 1 diabetes, pregnancy, lactation, a former eye surgery, age older than 50 years and those with higher baseline crp

Intervention groups

The study has a group that includes patients referring to the endocrinology clinic of Jahrom University of Medical Sciences. For people with serum levels of 25 hydroxyvitamin D3 less than 20 ng / ml, standard treatment with vitamin D (for 8 weeks each week, 50,000 units of vitamin D vitamin Zahravi) is started. After the end of the treatment period, the serum level of 25

hydroxyvitamin D3 and the dry eye parameters of all patients under study are checked again.

Main outcome variables

Tear breakup time test, Schirmer test results, Ocular Surface Disease Index score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200615047785N1**

Registration date: **2020-06-25, 1399/04/05**

Registration timing: **retrospective**

Last update: **2020-06-25, 1399/04/05**

Update count: **0**

Registration date

2020-06-25, 1399/04/05

Registrant information

Name

salma Ahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5434 0409

Email address

salmaahi.61@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-05-23, 1394/03/02

Expected recruitment end date

2016-03-31, 1395/01/12

Actual recruitment start date

2015-06-02, 1394/03/12

Actual recruitment end date

2016-05-30, 1395/03/10

Trial completion date

2016-06-04, 1395/03/15

Scientific title

Prevalence of dry eye in vitamin D deficiency patients that referred to the Jahrom Honary Clinic and the effect of vitamin D treatment on the dry eye parameters in 1394-1395

Public title

effect of vitamin D treatment on the dry eye parameters in 1394-1395

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients referred to the endocrinology clinic of Jahrom University of Medical Sciences with abnormal serum levels of 25OHD

Exclusion criteria:

Patients with SS (Sjogren's Syndrome) or with thyroid disease Having a history of other systemic rheumatic diseases Vitamin A deficiency Glucocorticoid, antidepressant, contraceptive, estrogen People with vitamin B12 deficiency, eye surface disorders and contact lenses, type 1 diabetes Pregnancy, lactation Has a history of eye surgery Individuals with crp above the baseline

Age

To **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **47**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Jahrom University of Medical Sciences Ethics Committee

Street address

Jahrom - Ostad Motahhari St. - After the School of Nursing - Jahrom University of Medical Sciences - Pardis Site

City

jahrom

Province

Fars

Postal code

4619974148

Approval date

2016-05-25, 1395/03/05

Ethics committee reference number

IR.JUMS.REC.1395.035

Health conditions studied**1****Description of health condition studied**

dry eye

ICD-10 code

H04.1

ICD-10 code description

Other disorders of lacrimal gland

2**Description of health condition studied**

Vitamin D deficiency

ICD-10 code

E55

ICD-10 code description

Vitamin D deficiency

Primary outcomes**1****Description**

eye dry

Timepoint

Measure the dryness of the eye at the beginning of the study (before the intervention) and 8 weeks after taking vitamin D tablets

Method of measurement

Using Schirmer's paper in the lower fornix and measuring its wetting rate, TBUT test result (using fluorescein paper in the lower fornix and measuring the discontinuity time of the lacrimal layer), dry eye score in the OSDI questionnaire

Secondary outcomes

1

Description

Serum level 25OHD

Timepoint

At the beginning of the study (before the start of the intervention) and 8 weeks after the intervention

Method of measurement

Blood sampling and blood tests

Intervention groups

1

Description

Intervention group: Visitors to Jahrom University of Medical Sciences' Endocrinology and Ophthalmology Clinic, who also suffer from serum deficiency of 25OHD and dry eye, and the intervention of the present study is The standard treatment for vitamin D (for 8 weeks each week is one 50,000-unit vitamin D tablet from Zahrawi).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology Clinic of Jahrom University of Medical Sciences

Full name of responsible person

Salma Ahi

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences Vice Chancellor for Research

Full name of responsible person

Kavoos Solhjoo

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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

Jahrom University of Medical Sciences Vice Chancellor for Research

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

Jahrom University of Medical Sciences

Full name of responsible person

Salma Ahi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Fax**Email**

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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

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

Data that includes the names and surnames of those present in the study, where they live, and their phone numbers will be kept strictly confidential and will not be published.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Everyone, در

Under which criteria data/document could be used

If other researchers want to do more research in this area, they will be provided with ethical considerations.

From where data/document is obtainable

Jahrom University of Medical Sciences

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

The request for data must be sent in writing to the ethics committee of Jahrom University of Medical Sciences.

Comments