Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
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
Phone
+98 71 5434 0409
Email
salmaahi.61@gmail.com

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
Street address
Jahrom - Ostad Motahhari St. - After the School of Nursing - Jahrom University of Medical Sciences - Pardis site
City
Jahrom
Province
Fars
Postal code
7414846199
Phone
+98 71 5434 0409
Email
salmaahi.61@gmail.com
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
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
Phone
+98 71 5434 0409
Fax
Email
salmaahi.61@gmail.com

Person responsible for scientific 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

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

Phone
+98 71 5434 0409

Fax

Email
salmaahi.61@gmail.com

Person responsible for updating data

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

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

Phone
+98 71 5434 0409

Fax

Email
salmaahi.61@gmail.com

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
Everyoneدر

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