Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Effect of Vitamin D, Omega 3 and their combination in treatment of 7-15 years old children with enuresis

Protocol summary

Summary

The study aim is to determine the effect of vitamin D, omega3 and their combination in treatment of 7-15 years old children with enuresis and it is a randomized, double-blind, placebo-controlled, single-center study . The study population is children 7-15 years old with enuresis whom will excluded if they do not take their supplement as prescribed or if they are not satisfied to continue and routine treatment will done for them . sample size is 180 person.In the first visit urinalysis and serum calcium tests are written. In the patient`s second visit in case of normal test results the supplement`s packages are given to the patients by researcher. In this study, patients and researchers remain unaware of the content of the package. The effect of 2 months vitamin D , omega 3 or both of them on enuresis treatment will checked . we expect that the number of wet nights in week decrease during these 2 months.

General information

Acronym

NE

IRCT registration information

IRCT registration number: **IRCT2015062222868N1**
Registration date: **2015-09-09, 1394/06/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-09-09, 1394/06/18

Registrant information

Name

elham rahmani

Name of organization / entity

school of nutrition and food science

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 1001

Email address

stud2300111111@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

shiraz university of medical science

Expected recruitment start date

2015-06-27, 1394/04/06

Expected recruitment end date

2015-12-27, 1394/10/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Vitamin D, Omega 3 and their combination in treatment of 7-15 years old children with enuresis

Public title

Effect of Vitamin D and Omega 3 in treatment of children with enuresis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 7-15; the tendency of parents to participate in the project and signing the consent form; the diagnosis of enuresis in child exclusion criteria: high serum calcium; high ratio of urine calcium to creatinin ; diabetics;

Age

From **7 years** old to **15 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences
Street address
Zand street , central building, 7th floor
City
Shiraz
Postal code
Approval date
2015-06-21, 1394/03/31
Ethics committee reference number
94-7513IR.SUMS.REC.1394.39

Health conditions studied

1

Description of health condition studied
nocturnal enuresis
ICD-10 code
F98.0
ICD-10 code description
Nonorganic enuresis

Primary outcomes

1

Description
Nocturnal enuresis
Timepoint
every week during 2 months intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
serum 1,25 (OH)2 vitaminD level
Timepoint
before study and at the end of study
Method of measurement
blood test

2

Description
urine prostaglandin E2 level
Timepoint
before and after intervention
Method of measurement
urine test

Intervention groups

1

Description
intervention group1: vitamin D3 supplement 1000 IU,1 tablet per day during 2 months and omega3 placebo capsule,1 capsule per day for 2 months
Category
Treatment - Drugs

2

Description
Intervention group 3: vitamin D3 supplement 1000 IU,1 tablet per day during 2 months and omega3 supplement 1000 mg , 1 capsule per day for 2 months
Category
Treatment - Drugs

3

Description
control group: placebo tablets of vitamin D3 ,1 tablet per day for 2 months and placebo capsule of omega 3 , 1 capsule per day for 2 months
Category
Treatment - Drugs

4

Description
Intervention group 2: omega3 supplement 1000 mg , 1 capsule per day for 2 months and vitamin d3 placebo tablet 1 tablet per day for 2 month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza clinic
Full name of responsible person
Elham Rahmani
Street address
6th floor, Imam Reza clinic, Namazi square
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr.Masum Masumpour
Street address
Zand street,central building of Shiraz Univercity of Medical Sciense , 7th floor
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
School Of Nutrition and Food Science
Full name of responsible person
Elham Rahmani
Position
Postgraduate student
Other areas of specialty/work
Street address
Razi.BLVD.school of nutrition and food science
City
Shiraz
Postal code
Phone
+98 71 3725 1001
Fax
Email
stud2300111111@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
school of nutrition and food sciense
Full name of responsible person
Dr.mohammad hassan eftekhari
Position
PhD
Other areas of specialty/work
Street address
Razi.BLVD,school of nutrition and food sciense
City
Shiraz
Postal code
Phone
+98 71 3725 1001
Fax
Email
eftekharim@sums.ac.ir
Web page address
http://scnutrition.sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
school of nutrition and food science
Full name of responsible person
Elham rahmani
Position
postgraguated student
Other areas of specialty/work
Street address
Razi,BLVD,school of nutrition and food science
City
shiraz
Postal code
Phone
+98 71 3725 1001
Fax
Email
Web page address
http://scnutrition.sums.ac.ir/

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty