

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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 Science , 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**

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

PhD

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Person responsible for updating data

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Elham rahmani

Position

postgraguated student

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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