

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

The Effect of Vitamin D on Nephrotic Syndrome in Children

Protocol summary

Study aim

The Effect of Vitamin D on Nephrotic Syndrome in Children

Design

This assessment is a clinical trial in Phase 3, children diagnosed with nephrotic syndrome that have been verified by pediatric specialist, are considered as study group. In this study, 60 children who meet the criteria are selected. Patients are categorized based on blocked randomization method, 30 children in the intervention group and 30 children in the control group. Accordingly, at the beginning of the diagnosis and 1 months after the start of treatment, the condition of the nephrotic syndrome is evaluated by signs and symptoms.

Settings and conduct

This study was carried out as a clinical trial at the Pediatric Clinic of Amir Kabir Hospital in Arak, Also the study will also be single blinded in which patients will be blinded in study.

Participants/Inclusion and exclusion criteria

Inclusion criteria is the only Nephrotic Syndrome, while patients who are not available during the next year to refer to the facility for follow-up or have other underlying conditions (such as hematology diseases or any other chronic disease), or intake drug for another illness, were excluded.

Intervention groups

In intervention group, in addition to the usual treatment of nephrotic syndrome (corticosteroid), we also used vitamin D, in which vitamin D is administered as an ampoule of 300,000 units, with a volume of one cc and 5 cc of olive oil is dissolved and injected, in addition in control group we used the usual treatment for Nephrotic Syndrome is 60 mg / m² / day is 60 mg of prednisolone (maximum dose of 80 mg / m² / day) for 4-6 weeks, which is used in the control group.

Main outcome variables

Signs of Nephrotic Syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130518013366N11**

Registration date: **2019-03-11, 1397/12/20**

Registration timing: **prospective**

Last update: **2019-03-11, 1397/12/20**

Update count: **0**

Registration date

2019-03-11, 1397/12/20

Registrant information

Name

Parsa Yousefi Chaijan

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1312 1964

Email address

dr.yousefi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-05, 1398/01/16

Expected recruitment end date

2019-10-08, 1398/07/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Vitamin D on Nephrotic Syndrome in Children

Public title

Vitamin D in Nephrotic Syndrome in Children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Affected to Nephrotic Syndrome

Exclusion criteria:

Patients who were not available during the next year and can not go to the center for follow-up treatment Patients with other underlying illnesses

Age

To **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomization we will use the block method, Accordingly, the patients under study are divided into two groups. The allocation of patients in two groups was based on demographic characteristics and their matching. Based on this, after considering the patients' demographic data, patients were divided into two equal groups of patients, they enrolled in the study and performed desired intervention on them.

Blinding (investigator's opinion)

Single blinded

Blinding description

This means that patients in groups do not know the used drugs, and drugs has similar packaging.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Sardasht

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2018-12-29, 1397/10/08

Ethics committee reference number

IR.ARAKMU.REC.1397.271

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

Nephrotic Syndrome

ICD-10 code

N04

ICD-10 code description

Nephrotic syndrome

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

Signs of Nephrotic Syndrome

Timepoint

Before treatment and 2 months after the administration of vitamin D

Method of measurement

Urine and blood test and clinical examination

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In these patients, in addition to the usual treatment of nephrotic syndrome (corticosteroid), we also used vitamin D, in which vitamin D is administered as an ampoule of 300,000 units, with a volume of one cc and 5 cc of olive oil is dissolved and injected.

Category

Treatment - Drugs

2**Description**

Control group: The usual treatment for Nephrotic Syndrome is 60 mg / m² / day is 60 mg of prednisolone (maximum dose of 80 mg / m² / day) for 4-6 weeks, which is used in the control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Pediatrics, Amir Kabir Hospital

Full name of responsible person

Shahriar Hasanzadeh

Street address

3819693345, Amir Kabir Hospital, Basij Square, Arak.

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Ali Arash Anoushirvani

Street address

3819693345, Vice Chancellor for Research, Arak
University of Medical Sciences, Sardasht, Arak.

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arashanoushirvani@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Shahriar Hasanzadeh

Position

Pediatric resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatric

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Parsa Yousefichaijan

Position

Associate Professor of Pediatric Nephrology

Latest degree

Subspecialist

Other areas of specialty/work

Pediatric Nephrology

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Hasan Taherahmadi

Position

Assistant Professor of Pediatric Diseases

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available