

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effectiveness of vitamin D supplement in prevention of urinary tract infections in children with recurrent urinary tract infection

Protocol summary

Summary

This randomized, triple-blind, placebo-controlled clinical trial was conducted in 2014 among 68 children and adolescents with recurrent UTI, referred to nephrology clinics of AlZahra and Emam Hossien hospitals, affiliated to Isfahan University of Medical Sciences and the private clinics of pediatrics nephrologists in Isfahan city. Patients were selected by simple randomized method. Participants were randomly allocated in two intervention and placebo groups. Patients in intervention group received oral vitamin D drop(DITHRECOL) which was diluted with paraffin with a dose of 1000IU/daily supplied by Caspian tamin pharmaceutical company (Tehran-Iran) and placebo (paraffin dickflussig.Art.7160.)supplied by Merk(Germany). Medication or placebo was for six months. The patients were followed up monthly for recurrence of UTI and for reassurance on their compliance for receiving the supplement and placebo. In addition to monthly follow up ,if patients presented with any sign and symptoms of UTI ,urine analysis and culture were performed. Demographic characteristics of each patient were recorded before intervention. The level of serum vitamin D before and after study and the frequency of UTI during the trial were recorded for each patient and compared between intervention and placebo groups. Based on serum vitamin D level, children were classified as having vitamin D deficiency ($\leq 19\text{ng/ml}$), insufficiency ($20\text{-}30\text{ng/ml}$) and adequacy ($>30\text{ng/ml}$). Patients in each group were compared according to this classification before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052221968N2**

Registration date: **2017-08-10, 1396/05/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-10, 1396/05/19

Registrant information

Name

Alireza Merrikhi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 3669 1362

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Isfahan University of Medical Sciences

Expected recruitment start date

2014-04-01, 1393/01/12

Expected recruitment end date

2014-12-01, 1393/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of vitamin D supplement in prevention of urinary tract infections in children with recurrent urinary tract infection

Public title

Effectiveness of vitamin D supplement in prevention of recurrent urinary tract infections in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Children with documented recurrent UTI who were not in the active phase of UTI ; Children who had no anatomical defects; renal stone; neurogenic bladder; higher grade of reflux ($\geq$ grade II); obstructive uropathies and congenital or acquired immune deficiency; Circumcised boys
Exclusion criteria: Patients without appropriate compliance for regular follow up or treatment

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar jerib street, Isfahan University of Medical Sciences

City

Isfahan

Postal code

81746-73461

Approval date

2014-02-07, 1392/11/18

Ethics committee reference number

393734

Health conditions studied

1

Description of health condition studied

Urinary tract infection

ICD-10 code

N39.0

ICD-10 code description

Urinary tract infection, site not specified

Primary outcomes

1

Description

Urinary track infection

Timepoint

monthly

Method of measurement

urine analysis

Secondary outcomes

1

Description

frequency of reccurent urinary track infrvtion

Timepoint

6 months after intervention

Method of measurement

Urine analysis

Intervention groups

1

Description

control group: placebo (paraffin dickflussig, Art. 7160, germany) for six months

Category

Placebo

2

Description

Intervention group: oral vitamin D drop (DITHRECOL) which was diluted with paraffin with a dose of 1000 IU/daily for six months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emem Hossein childrens' hospital

Full name of responsible person

Street address

City

Isfahan

2

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person**Street address****City**

Isfahan

3

Recruitment center

Name of recruitment center

Private clinics of pediatrics nephrologists

Full name of responsible person**Street address****City**

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Merrikhi

Street address

Hezar jerib street, Isfahan University of Medical Sciences

City

Isfahan

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

Yes

Title of funding source

Vice Chancellor for Research of Isfahan 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**

Isfahan University of Medical Sciences

Full name of responsible person

Elahe Ziaei

Position

pediatrics specialist

Other areas of specialty/work**Street address**

Emam Khomeyni street, Emam Hossien childrens' Hospital

City

Isfahan

Postal code**Phone**

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Fax**Email**

e.ziaei64@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Isfahan university of Medical Sciences

Full name of responsible person

Alireza Merrikhi

Position

Associate professor of Pediatric Nephrology

Other areas of specialty/work**Street address**

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Full name of responsible person

Alireza Merrikhi

Position**Other areas of specialty/work****Street address****City**

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Postal code**Phone**

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Fax**Email****Web page address**

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