

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of omega-3 on the prevention of renal scarring according to dimercaptosuccinic acid (DMSA) findings in children with acute pyelonephritis

Protocol summary

Summary

Urinary tract infection (UTI) is a common problem in pediatric population that can cause renal scarring, and eventually, chronic kidney failure. Urinary tract infection occurs in 3% to 5% of girls and 1% of boys during childhood. Pyelonephritis is an inflammatory process in kidney that results in persistent injury to kidney. Virulence factors and defense response of host play important role in pyelonephritis and inflammatory response. Omega-3 is a supplement that has anti-inflammatory and antioxidant effect. This double blinded randomized clinical trial (patients and researchers are unaware of when the experimental medicine has been given) on 60 children with acute pyelonephritis were performed. Children aged 1 month to 10 years with positive urine culture, clinical findings, and 99mTc-dimercaptosuccinic acid (DMSA) scintigraphy-based evidence in favor of acute pyelonephritis were enrolled into a clinical trial. Patients with neurogenic bladder, systemic hypertension, obstructive uropathy and high grade vesicoureteral are excluded. Patients in intervention group are administered omega-3 based on body weight in divided doses in addition to antibiotic regimens and patients in control group received antibiotic regimens without omega-3. Primary outcome is the development of renal scar by doing DMSA renal scan six months after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062922965N1**
Registration date: **2015-09-23, 1394/07/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-23, 1394/07/01

Registrant information

Name

Maryam Mehrpoya

Name of organization / entity

School of Pharmacy, Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Hamadan University of Medical Sciences

Expected recruitment start date

2014-01-01, 1392/10/11

Expected recruitment end date

2015-11-01, 1394/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega-3 on the prevention of renal scarring according to dimercaptosuccinic acid (DMSA) findings in children with acute pyelonephritis

Public title

Omega-3 in prevention of renal scars in pyelonephritis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Children aged between 1 months and 10 years old with a definite diagnosis of acute pyelonephritis based on clinical; laboratory and 99m Tc-DMSA renal scan finding
Exclusion criteria: Children with neurogenic bladder; systemic hypertension; obstructive uropathy; and high grade vesicoureteral (grade 4-5)

Age

From **1 month** old to **10 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Both the subjects participating and the researchers are unaware of when the experimental medication or procedure has been given

Secondary Ids

1

Registry name

clinicaltrials.gov

Secondary trial Id

NCT02192580

Registration date

2014-07-13, 1393/04/22

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Khajerashid junction, Ayatollah kashani boulevard, Hamadan University of Medical Sciences

City

Hamadan

Postal code

Approval date

2014-05-22, 1393/03/01

Ethics committee reference number

249

Health conditions studied

1

Description of health condition studied

Pyelonephritis

ICD-10 code

N12

ICD-10 code description

Tubulo-interstitial nephritis, not specified as acute or chronic

Primary outcomes

1

Description

Evaluation of renal Scar

Timepoint

Six months after intervention

Method of measurement

using nuclear scan 99mTc-DMSA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: approved antibiotic + omega-3 with different doses based on body weight

Category

Prevention

2

Description

Control Group: Only antibiotic therapy without omega-3

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Street address

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Hamadan University of Medical Sciences

Full name of responsible person

Alireza Ahmadi

Street address

Hamedan University of Medical Sciences, Shahid Fahmide avenue, Hamedan

City

Hamadan

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 Hamadan 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

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

Maryam Mehrpooya

Position

Assistant Professor

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Fax**Email**

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Web page address

Person responsible for updating data

Contact

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