

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The Effect of Vitamin E and Vitamin A on the prevention of renal scarring according to DMSA findings in children with acute pyelonephritis

Protocol summary

Summary

We evaluated the effect of Vitamin A (anti-inflammatory) and Vitamin E (antioxidant) in addition to antibiotic in children who suffered of acute pyelonephritis on prevention of renal scarring. In this study, 60 children with acute pyelonephritis admitted in Ali-Asghar children hospital were enrolled into a clinical trial. The patients were assigned into one of the following three groups. The control groups received antibiotic as Keflin, 100mg/kg/day, every 6 hours and Amikacin, 15mg/kg/day, every 8 hours. In the intervention groups, vitamin A (1500 Unit/kg/day, for 10 days) or vitamin E (15-25 IU/day, for 10 days) was added to the antibiotics. The development of renal scar was evaluated by doing DMSA renal scan on the second day of admission and six months after the intervention and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103256102N1**

Registration date: **2011-04-29, 1390/02/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-29, 1390/02/09

Registrant information

Name

Nakysa Hooman

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2304 6211

Email address

nhooman@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2004-09-01, 1383/06/11

Expected recruitment end date

2006-10-31, 1385/08/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Vitamin E and Vitamin A on the prevention of renal scarring according to DMSA findings in children with acute pyelonephritis

Public title

Vitamins in Prevention of Renal Scars in Pyelonephritis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: positive urine culture, clinical findings, and 99mTC-DMSA criteria of APN Exclusion criteria: presence of neurogenic bladder, systemic hypertension, obstructive uropathy, high grade vesico-ureteral reflux (Grade 4-5)

Age

From **1 year** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
601, 6th floor, Central building of TUMS, Gods St.,
Keshavarz Blvd.

City
Tehran

Postal code
1417653761

Approval date
2005-11-21, 1384/08/30

Ethics committee reference number
7951-16,4,83

Health conditions studied

1

Description of health condition studied
Acute Pyelonephritis

ICD-10 code
N39.0

ICD-10 code description
Urinary tract infection, site not specified

Primary outcomes

1

Description
Renal scar

Timepoint
at least 6 month apart

Method of measurement
Criteria of developing scar in 99mTC-DMSA

Secondary outcomes

1

Description
intolerance to vitamins

Timepoint
daily

Method of measurement
daily clinical observation

2

Description
no response to antibiotic therapy

Timepoint
daily

Method of measurement
urine culture at the 3rd day, clinical observation for fever
and general condition

3

Description
acute renal failure

Timepoint
daily at the time of hospitalization

Method of measurement
urine output, serum creatinine, blood pressure
measurement

Intervention groups

1

Description
Vitamin A group: Keflin or Ampicillin 100mg/kg/day qid
and Amikacin 15mg/kg/day, tid for 10 days, as well as
vitamin A, 1500 U/kg/day for 10 days

Category
Treatment - Drugs

2

Description
Control group: Keflin or Ampicillin 100mg/kg/day qid as
well as Amikacin 15mg/kg/day, tid for 10 days, or
appropriate to antibiogram if it is available

Category
Treatment - Drugs

3

Description
Vitamin E group: A group: Keflin or Ampicillin
100mg/kg/day qid and Amikacin 15mg/kg/day, tid for 10
days, as well as vitamin E 15-25U/day, for 10 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali- Asghar Children Hospital

Full name of responsible person

Street address

Vahid dasgerdi st.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical sciences

Full name of responsible person

Dr Seyed Ahmad Rezaii

Street address

601, 6th floor, Central building TUMS, Gods st.,
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City

Tehran

Grant name

Grant code / Reference number

2198-84.8.30

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Behnam Sobooti

Position

Resident of Pediatric

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran Univesity of Medical Sciences

Full name of responsible person

Nakysa Hooman

Position

Pediatric Nephrology

Other areas of specialty/work

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<http://medicine.tums.ac.ir/fa/ShowHospital.aspx?Lt=1&Li=1333>

Person responsible for updating data

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Full name of responsible person

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Position

Resident of Pediatric

Other areas of specialty/work

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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