Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Effect of vitamin E supplementation in the treatment of UTI in children

Protocol summary

Summary
In this double blind randomized controlled trial which took place in Arak , Amirkabir Hospital , 152 children who got divided into two groups of case and control were treated with antibiotics for 14 days. In addition the case group received vitamin E supplementation adjacent to therapy. After 14 days we assessed them for time of negative culture results and cessation of clinical signs and symptoms of UTI.

General information

Acronym
Vitamin E and UTI in children
IRCT registration information
IRCT registration number: **IRCT201305199766N2**
Registration date: **2013-06-12, 1392/03/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2013-06-12, 1392/03/22

Registrant information
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Mohammadreza Firouzifar
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Tehran University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source
Arak University of Medical Sciences

Expected recruitment start date
2012-12-20, 1391/09/30
Expected recruitment end date
2013-12-21, 1392/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of vitamin E supplementation in the treatment of UTI in children

Public title
Effect of vitamin E in the treatment of UTI in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criterion: the diagnosis of urinary tract infection. Exclusion criteria: genito urinary anomalies; sacrum anomalies; baseline scar on kidneys; disrupted VCUG; persistent bacteriuaria; history of recurrent UTI's; bad compliance to therapy; positive cultures with more than one organism and renal calculi.
Age
From **3 years** old to **12 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **152**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description

Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Arak University of Medical Sciences Ethics Committee
Street address
Arak University of Medical Sciences Ethics Committee,Arak University of Medical Sciences, Arak, Iran
City
Arak
Postal code
Approval date
2012-11-28, 1391/09/08
Ethics committee reference number
91-138-8

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
time of fever cessation
Timepoint
day
Method of measurement
counting the days till there is no fever present

2

Description
time of dysuria cessation
Timepoint
day
Method of measurement
counting the days till there is no dysuria present

3

Description
time of frequency cessation
Timepoint
day
Method of measurement
counting the days till there is no frequency present

4

Description
time of urgency cessation
Timepoint
day
Method of measurement
counting the days till there is no urgency present

5

Description
time of dribbling cessation
Timepoint
day
Method of measurement
counting the days till there is no dribbling present

6

Description
time of incontinence cessation
Timepoint
day
Method of measurement
counting the days till there is no incontinence present

7

Description
time of abdominal pain cessation
Timepoint
day
Method of measurement
counting the days till there is no abdominal pain present

Secondary outcomes

1

Description
urine culture
Timepoint
48 h after the start of treatment and 7-10 days post treatment
Method of measurement
it is positive if there are more than 100000 CFU

Intervention groups

1

Description
control : 50-75 mg/kg/day of IV ceftriaxone for inpatients

and cefixime syrup 8mg/kg/day for outpatients for overall time of 14 days

Category

Treatment - Drugs

2

Description

case :50-75 mg/kg/day of IV ceftriaxone for inpatients and cefixime syrup 8mg/kg/day for outpatients for overall time of 14 days + 100 units Vitamin E for 14 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Amirkabir Hospital

Full name of responsible person

Dr. Parsa Yousefi

Street address

Dept of Pediatrics, Amirkabir hospital. alamolhoda st.

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Davood Hekmatpoo

Street address

Arak University of Mecial Sciences , Basij Sq,Arak

City

Arak

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

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

Arak University of Medical Sciences

Full name of responsible person

Dr Sara Rasti

Position

MD, resident of pediatrics

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Pediatric Nephrologist

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Person responsible for updating data

Contact

Name of organization / entity

Student research committee, Arak University of Medical sciences

Full name of responsible person

Mohammad Reza Firouzifar

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Student of medicine

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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