Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Comparing the effect of Cranberry and Nitrofurantoin on recurrent urinary tract infection in children

Protocol summary

Study aim
Survey of cranberry capsule on prevention of recurrent urinary tract infection in children and its replacement with routine antibiotics

Design
A randomized clinical trial with control group, parallel group design and without blinding, with a sample size of 50 patients

Settings and conduct
The study place will be the Nephrology clinic of Sabzevar Heshmatie Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children with recurrent urinary tract infection; Written consent from parents.Non-inclusion criteria: Children less than one month; Patients who are unable to use the medication in question due to the patient's departure from the usual route to complication or deterioration of the patient's general condition.

Intervention groups
Intervention group: Children with recurrent urinary tract infection will be treated using 300 mg cranberry capsule daily for one month. Control group: Children with recurrent urinary tract infection will receive 10 mg /kg Nitrofurantoin (an antibiotic) daily for 1 month.

Main outcome variables
Urinary tract infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191207045640N1**
Registration date: **2020-02-11, 1398/11/22**
Registration timing: **retrospective**

Last update: **2020-02-11, 1398/11/22**
Update count: **0**

Registration date
2020-02-11, 1398/11/22

Registrant information
Name
Zahra Boluki
Name of organization / entity
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Iran (Islamic Republic of)
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+98 51 4262 7414
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zahra.boluki@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-05, 1398/10/15

Expected recruitment end date
2020-01-20, 1398/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of Cranberry and Nitrofurantoin on recurrent urinary tract infection in children

Public title
Surveying cranberry effect on urinary tract infection in children

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
All children with recurrent urinary tract infection Written parental consent

Exclusion criteria:
Children under the age of one month Parental dissatisfaction Patients who are unable to use the medication in question due to the patient's departure from the usual route to complication or deterioration

Age
From **1 month** old to **16 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to do simple random allocation, the numbered cards with odds and even numbers are placed in a bag and an individual unaware of the numbers on the cards will give the cards to the parent. Therefor the patients will be randomly assigned to the intervention and control groups.

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
Ethics committee of Sabzevar University of Medical Sciences

Street address
Heshmati Hospital, Assad Abadi street, Sabzavar

City
Sabzevar

Province
Razavi Khorasan

Postal code
9319719746

Approval date
2019-12-08, 1398/09/17

Ethics committee reference number
IR.MEDSAB.REC.1398.073

Health conditions studied

1

Description of health condition studied
Recurrent urinary tract infection

ICD-10 code
N39.0

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

Primary outcomes

1

Description
Urinary tract infection

Timepoint
One week after treatment, then every one month up to three months and then every two months up to 6 months

Method of measurement
Urine analysis and urine culture

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Blueberry capsule 300 mg once daily for three months after treatment for UTI and for children who cannot use the capsule, the mother is asked to dissolve and use the contents of the capsule in water.

Category
Treatment - Drugs

2

Description
Control group: Nitrofurantoin antibiotic with prophylactic dose (one third of therapeutic dose) 1 mg / kg daily (maximum daily dose 100 mg) in the form of 50 mg tablets Mehr Daro Company based on baby weight for three months They will receive urinary tract infection after treatment.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Heshmati Specialty Hospital

Full name of responsible person
Zahra Boluki

Street address
Assad Abadi street

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Hosen Shariatmadari
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vc.dmr@medsab.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Zahra Boluki
Position
Intern
Latest degree
A Level or less
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Medical Intern
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Person responsible for updating data

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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
Yes - There is 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
Title and more details about the data/document
I haven't decided yet - its release schedule is still unclear
When the data will become available and for how long
I haven't decided yet - its release schedule is still unclear
To whom data/document is available
I haven't decided yet - its release schedule is still unclear
Under which criteria data/document could be used
I haven't decided yet - its release schedule is still unclear
From where data/document is obtainable
I haven't decided yet - its release schedule is still unclear
What processes are involved for a request to access data/document
I haven't decided yet - its release schedule is still unclear
Comments