Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of effect of Omega 3 on UTI (Cystitis and pyelonephritis) Symptoms

Protocol summary

Study aim
Determining the effect of omega-3 on the improvement of urinary infection symptoms
Design
The present study is a clinical trial with a control group, with parallel groups, randomized (using block randomization), phase 3 on 100 patients.
Settings and conduct
In this double-blind randomization clinical trial, children with a definite diagnosis of urinary tract infection referred to Amirkabir Arak Hospital will be divided into two identical omega-3 groups by block randomization. In this study, the participants (by placebo pills) and the outcome assessor (by patient coding) will be blinded. In each group, drug treatment will be prescribed daily for 10 days. Finally, two groups will be evaluated in terms of study results.
Participants/Inclusion and exclusion criteria
Inclusion Criteria: children aged 4-18 years with urinary tract infection; Consent to participate in the study
Exclusion Criteria: existence of underlying kidney and liver disease; Sensitivity to omega-3
Intervention groups
Omega-3 group: In addition to receiving standard treatment (antibiotic suitable for symptoms, age and gender), children will receive mercury-free Omega-3 capsules produced by Zahrawi company for 10 days.
Control group: In this group, children will receive only the standard treatment for 10 days.
Main outcome variables
Fever, Dysuria, frequency, abdominal pain, urinary incontinence

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191104045328N22**
Registration date: **2024-05-21, 1403/03/01**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-21, 1403/03/01**
Update count: **0**
Registration date
2024-05-21, 1403/03/01

Registrant information
Name
Amin Haji seyyed hoseini
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 86 3366 7583
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amin.medstu@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-05-21, 1403/03/01
Expected recruitment end date
2024-08-22, 1403/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of effect of Omega 3 on UTI (Cystitis and pyelonephritis) Symptoms

Public title
effect of Omega 3 on UTI
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children 4-18 years old with urinary tract infection
Consent to participate in the study

Exclusion criteria:

The presence of underlying kidney and liver disease
Sensitivity to omega-3

Age

From **4 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be assigned to two intervention and control groups based on the randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate the samples. In this way, using the site www.sealedenvelope.com, blocks of 8 letters A and B are randomly generated based on the sample size. The order of placement of letters A and B in each block from the first block to the last block is considered as a randomization sequence. The production of these blocks and their random sequence is completely done by this site and the researcher does not know how they are sequenced.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. In this way, the intervention group will receive omega-3 along with routine treatment for urinary infection, while the placebo group will receive a similar placebo instead of omega-3. Therefore, the participants do not know the type of medicine received. On the other hand, prescribing the drugs is the responsibility of the supervisor, and the student, who evaluates the information, does not know about the grouping.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2023-12-31, 1402/10/10

Ethics committee reference number

IR.ARAKMU.REC.1402.200

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

Fever

Timepoint

The beginning and end of treatment

Method of measurement

Mercury Therommeter

2

Description

Dysuria

Timepoint

The beginning and end of treatment

Method of measurement

Take a history

3

Description

Frequency

Timepoint

The beginning and end of treatment

Method of measurement

Take a history

4

Description

abdominal pain

Timepoint

The beginning and end of treatment

Method of measurement

Take a history

5

Description

urinary incontinence

Timepoint

The beginning and end of treatment

Method of measurement

Take a history

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to receiving standard treatment (antibiotic suitable for symptoms, age and gender), children will receive mercury-free Omega-3 capsules produced by Zahrawi company for 10 days.

Category

Treatment - Drugs

2

Description

Control group: In this group, children will receive only the standard treatment for 10 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Amir Kabir Hospital

Full name of responsible person

Dr. Manijeh Kahbazi

Street address

Vice Chancellor for Education, Amir Kabir Hospital, Arak, Iran

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3819691187

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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

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

Arak University of Medical Sciences

Full name of responsible person

Dr. Manijeh Kahbazi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr. Parsa Yousefi Chaijan

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Arshia Toghra

Position
Student

Latest degree
A Level or less

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General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long
Access will be from 2024/09/20 to 2027/09/20 for 3 years.

To whom data/document is available
University researchers

Under which criteria data/document could be used
Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

From where data/document is obtainable
Academic researchers and university professors can request the use of data from Dr. Manijeh Kohbazi after contacting the relevant professor by message or email. Dr. Manijeh Kohbazi: Phone: 09181614351 Email: m_kahbazi77@yahoo.com Address: Arak, Amir Kabir Hospital, Hospital Education Vice-Chancellor

What processes are involved for a request to access data/document
Letter writing should be done with professors and universities.

Comments