Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Evaluation of responses to Omeprazole treatment in children with non-cardiac chest pain

Protocol summary

Study aim

Determination of response to omeprazole treatment in children with non-cardiac chest pain referred to Amir Kabir Hospital, Arak, Iran, 1997

Design

A single-blind randomized clinical trial study will be conducted on 144 children and adolescents aged 5-18 years with non-cardiac chest pain. Patients with inclusion criteria will be divided into two groups of 74 by using randomized block design. The first group will be children who will be considered as intervention group. One course of omeprazole 1mg / kg daily. A number is given before breakfast for two weeks. The second group includes children who will be considered as a control group and will be given placebo for the same period. After a 2-week study period, patients will be followed up and rechecked to determine if this treatment has been helpful.

Settings and conduct

A single-blind study is performed on patients referred to Amir Kabir Hospital in Arak. Children with non-cardiac chest pain were randomly assigned into two groups of omeprazole and control groups. Children and their families are not aware of the study group. Follow-up and response to treatment are also based on a checklist prepared on the first, seventh, and fourth days.

Participants/Inclusion and exclusion criteria

Chest pain in this study was continuous or recurrent pain that lasted for at least 2 weeks and for a maximum of 8 weeks. Children with a history of chest trauma or point tenderness will be excluded.

Intervention groups

The first group consists of children who will be considered as the intervention group. One course of omeprazole 1mg / kg daily is given one day before breakfast for two weeks. And they will be given placebo for the same period.

Main outcome variables

Severity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191208045655N1**
Registration date: **2019-12-25, 1398/10/04**
Registration timing: **retrospective**

Last update: **2019-12-25, 1398/10/04**
Update count: **0**

Registration date

2019-12-25, 1398/10/04

Registrant information

Name

Vahid Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3367 5904

Email address

vahid.heidari8818@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-06, 1397/09/15

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

2018-12-06, 1397/09/15

Actual recruitment end date

2019-03-11, 1397/12/20

Trial completion date

2019-03-11, 1397/12/20

Scientific title

Evaluation of responses to Omeprazole treatment in children with non-cardiac chest pain

Public title
The effect of omeprazole on pediatric chest pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Kids 5-18 years old Complain chest pain that lasts for at least 2 weeks
Exclusion criteria:
cardiac chest pain Patient unwillingness to continue collaborating in the study Duration of pain more than 8 weeks History of trauma to the chest point tenderness
Age
From **5 years** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **144**
Actual sample size reached: **144**
Randomization (investigator's opinion)
Randomized
Randomization description
In this clinical trial study, 144 patients, aged 5-18 years, referred to Amir Kabir Hospital in Arak, complaining of chest pain and having inclusion criteria, after obtaining informed consent. Patients were then randomly divided into two groups of omeprazole and control groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a single-blind randomized clinical trial in which children with non-cardiac chest pain will be divided into two equal groups. The first group is children who will be considered as the intervention group and will be given a course of treatment with omeprazole. The second group includes children who will be treated as a control group and given placebo for the same period. The blinding method in this study is that the children and their families are not aware of the study group. But the physician, clinician, and data analyst know the groups.
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
Payambar-e-azam University Complex, Sardasht Town
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2018-12-02, 1397/09/11
Ethics committee reference number
IR.ARAKMU.REC.1397.113

Health conditions studied

1

Description of health condition studied
Non-cardiac Chest Pain
ICD-10 code
R07.9
ICD-10 code description
Chest pain, unspecified

Primary outcomes

1

Description
Chest pain
Timepoint
First, seventh and fourteenth days
Method of measurement
Visual Analogue Scale of pain

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A course of treatment with omeprazole at a dose of 1mg / kg daily is prescribed for one week before breakfast for two weeks.
Category
Treatment - Drugs

2

Description
Control group: A placebo is given one number before breakfast for two weeks.
Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Amirkabir Hospital
Full name of responsible person
Vahid Heydari
Street address
Shiruodi St., Parastar Ave.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
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research@arakmu.ac.ir

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
Vahid Heydari
Position
Student
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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
Undecided - It is not yet known if there will be 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