

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the effect of single and twice daily administration of ranitidine in relief of morning abdominal pain and nausea in children

Protocol summary

Study aim

The effect of single and two doses ranitidine on nausea and morning abdominal pain in children

Design

In this study, the samples were selected among 3-15 year old children who were referred by parents to Hospital, with nausea and abdominal pain .minimum of 3 years were considered as the minimum age because children under 3 years of age were not able to express problems and complaints, and 15 years were considered as the maximum age range for pediatric patients. Due to the fact that patients are all referred with complaints of pain, administration of placebo is unacceptable. The subjects were randomly divided into two intervention groups including group 1 (treated with single dose ranitidine) and group 2 (ranitidine Bid). The two groups are matched in terms of age and gender. For each child, ranitidine is prescribed for a period of 4 weeks. In group 1, ranitidine was given a single dose of 2 mg/ kg before bed and in group 2, 2 mg/kg will be given twice daily to patients. Patients in each group in the second and sixth weeks after starting treatment are evaluated for the improvement of symptoms.

Settings and conduct

gorgan taleghani hospital

Participants/Inclusion and exclusion criteria

inclusion criteria in the study includes persistent or intermittent pain in the morning for more than two weeks at the upper abdominal area or nausea in the morning which has no non-GI cause and age between the of 15-3 years.

Intervention groups

effect of ranitidine single or two doses on children aged 3 to 15 years old with a complaint of nausea and abdominal pain in the morning.

Main outcome variables

Improve the pain and morning nausea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171211037830N2**

Registration date: **2018-07-05, 1397/04/14**

Registration timing: **retrospective**

Last update: **2018-07-05, 1397/04/14**

Update count: **0**

Registration date

2018-07-05, 1397/04/14

Registrant information

Name

Mohammad Sobhani Shahmirzadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3252 8435

Email address

sobhani@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-03-21, 1396/01/01

Actual recruitment end date

2018-03-20, 1396/12/29

Trial completion date

empty

Scientific title

Comparison of the effect of single and twice daily administration of ranitidine in relief of morning abdominal pain and nausea in children

Public title

Comparison of the effect of single and twice daily administration of ranitidine in relief of morning abdominal pain and nausea in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

abdominal pain and nausea

Exclusion criteria:

Nausea caused by extra-digestive system causes

Age

From **3 years** old to **15 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **150**

Actual sample size reached: **150**

Randomization (investigator's opinion)

Not 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

Ethics committee of Golestan University of Medical Sciences

Street address

Hirkan Blvd,Gorgan

City

Gorgan

Province

Golestan

Postal code

4916668197

Approval date

2017-04-21, 1396/02/01

Ethics committee reference number

Ir.Goums.REC.1396.240

Health conditions studied

1

Description of health condition studied

abdominal pain and nausea

ICD-10 code

R10.9

ICD-10 code description

Unspecified abdominal pain

Primary outcomes

1

Description

improvement in abdominal pain

Timepoint

Two weeks and four weeks after starting treatment

Method of measurement

Question from parents

2

Description

improvement in nausea

Timepoint

Question from parents

Method of measurement

improvement in nausea

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: single dose ranitidine

Category

Treatment - Drugs

2

Description

Intervention group: two dose ranitidine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Children Hospital in Gorgan

Full name of responsible person

Mohammad Sobhani Shahmirzadi

Street address

Taleghani Hospital, janbazan Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy of Research of Golestan University of Medical Sciences
Full name of responsible person
Mohammad Sobhani Shahmirzadi
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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

Deputy of Research of Golestan 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
Gorgan University of Medical Sciences
Full name of responsible person
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Position
Assistant professor

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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