

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of the effect of ranitidine syrup with Quince syrup in pediatric gastroesophageal reflux aged 12 to 48 months

Protocol summary

Study aim

Comparison of the effect of ranitidine syrup with Quince syrup in pediatric gastroesophageal reflux disease (GERD) patients aged 12 to 48 months with ranitidine syrup

Design

A double blind randomized controlled clinical trial in pediatric GERD patients aged 12 to 48 months. Patients are randomly selected on the basis of a quadrilateral block for use in one of the pharmaceutical forms. Total sample size: 80 patients in two treatment and control group

Settings and conduct

Participants were selected from pediatrics with GERD aged 12 to 48 months based on clinical manifestations and initial confirmation of pediatric gastroenterology referring to the gastroenterology clinic of Ghaem Hospital in Mashhad . After completing the initial history and the GSQ-YC questionnaire, consent form were filled by parents, then participants were follow up for 4 weeks. Data collection is done by using the GSQ-YC questionnaire. Participants are randomly divided on the basis of a quadrilateral block in one of the groups. The same type of bottles have been used for all interventions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 12 to 48 months with common symptoms of reflux disease (heartburn, regurgitation, vomiting, epigastric pain and appropriate weight loss) for at least 2 times a week. Exclusion criteria: People with complication of GERD or underlying disease (neurological, cardiac, pulmonary, liver and kidney) or mental retardation and people who have used other herbal remedies during this period.

Intervention groups

Participants were divided randomly into two groups. The control group received daily "Ranitidine syrup" and the placebo syrup and the case group received "Ranitidine syrup" and "Quince syrup"

Main outcome variables

Severity of vomiting; number of vomiting; severity of hiccups; frequency of hiccups; severity of abdominal pain; frequency of abdominal pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170501033750N2**
Registration date: **2018-04-20, 1397/01/31**
Registration timing: **retrospective**

Last update: **2018-04-20, 1397/01/31**

Update count: **0**

Registration date

2018-04-20, 1397/01/31

Registrant information

Name

maryam naeimi

Name of organization / entity

babol university of medical science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

governmental

Expected recruitment start date

2017-06-10, 1396/03/20

Expected recruitment end date

2018-01-19, 1396/10/29

Actual recruitment start date

2017-06-17, 1396/03/27

Actual recruitment end date

2018-01-10, 1396/10/20

Trial completion date

empty

Scientific title

Comparison of the effect of ranitidine syrup with Quince syrup in pediatric gastroesophageal reflux aged 12 to 48 months

Public title

The effect of Quince syrup in pediatric gastroesophageal reflux aged 12 to 48 months

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients in the age group of 12 to 48 months. People with at least 2 times a week with common symptoms of reflux disease (heartburn, regurgitation, vomiting, epigastric pain and appropriate weight loss for at least a month Those who are newly diagnosed or who have been suffering from reflux, have not taken any medications for at least one month and will want to start their treatment again

Exclusion criteria:

Patients with severe reflux disease (severe onset: symptoms of severe esophagitis, vomiting, life-threatening symptoms such as apnea, pneumonia, esophageal stricture and systemic diseases) due to the need for treatments Another intervention, including surgery or other medications, is withdrawn from the project because of ethical considerations (non-deprivation of the patient and non-risk for the volunteers) Children with a disease (neurological, cardiac, pulmonary, liver and kidney) or mental retardation People who have used other herbal remedies during this period People who need to use chemical drugs during the plan due to the specific disease People with a history of allergy to herbal medicines

Age

From **1 year** old to **4 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization in this study is quadruple

blocking method and the randomization unit is individual and tool is statistical software. The sequencing will be done by quadruple blocking. Concealing done by using similar form and size bottle for both groups, and neither the interventions nor the volunteers knows how to allocate the intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients are completely unaware of which drugs they received. Also, the investigator is completely unaware that the two groups received which drug

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

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Postal code

15.3.2017

Approval date

2017-03-15, 1395/12/25

Ethics committee reference number

Mubabol.hri.rec.1395.114

Health conditions studied**1****Description of health condition studied**

Gastro-oesophageal reflux

ICD-10 code

K21

ICD-10 code description

Gastro-esophageal reflux disease

Primary outcomes**1****Description**

Severity of nausea

Timepoint

A week before treatment, the second, fourth and sixth weeks after treatment

Method of measurement

GSQ-YC standard questionnaire

2

Description

Numbers of vomiting

Timepoint

A week before treatment, the second, fourth and sixth weeks of treatment

Method of measurement

GSQ-YC standard questionnaire

3

Description

Severity of hiccups

Timepoint

The beginning of the week, the second week, the fourth, the sixth

Method of measurement

GSQ-YC standard questionnaire

4

Description

Severity of abdominal pain

Timepoint

The beginning of the week, the second week, the fourth, the sixth

Method of measurement

GSQ-YC standard questionnaire

5

Description

Frequency of abdominal pain

Timepoint

The beginning of the week, the second week, the fourth, the sixth

Method of measurement

GSQ-YC standard questionnaire

6

Description

Severity of regurgitation

Timepoint

The beginning of the week, the second week, the fourth, the sixth

Method of measurement

GSQ-YC standard questionnaire

7

Description

Frequency of hiccups

Timepoint

The beginning of the week, the second week, the fourth, the sixth

Method of measurement

GSQ-YC standard questionnaire

Secondary outcomes

1

Description

Refuse to eat

Timepoint

The last week of treatment, the second week of the fourth and sixth treatment

Method of measurement

GSQ-YC standard questionnaire

2

Description

Inappropriate weighing

Timepoint

Before starting treatment and then finishing treatment for the sixth week

Method of measurement

Baby growth curve

3

Description

Swallowing disorder

Timepoint

Before starting treatment and during treatment until the 6th week

Method of measurement

GSQ-YC standard questionnaire

4

Description

side effects

Timepoint

Any time during treatment

Method of measurement

Baby Nurse Report

5

Description

Repeated use of anti-acid

Timepoint

First and second months of treatment

Method of measurement

Baby Nurse Report

Intervention groups

1

Description

The intervention group are given quince syrup twice daily with ranitidine syrup for 4 weeks.

Category

Treatment - Drugs

2

Description

The placebo control group are given sugar syrup twice daily with ranitidine syrup for 4 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastrointestinal clinic of Ghaem Hospital in Mashhad

Full name of responsible person

Maryam Naeimi

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Sponsors / Funding sources

1

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Maryam Naeimi

Position

Ph.D Student of Traditional Medicine

Latest degree

Medical doctor

Other areas of specialty/work

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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

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

Yes - There is 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

On the basis of the reliable questionnaire

When the data will become available and for how long

After article publication

To whom data/document is available

All people

Under which criteria data/document could be used

Published article according to Ph.D. thesis

From where data/document is obtainable

Babol university of medical sciences.timbabol@yahoo.com, 00981132194730

What processes are involved for a request to access data/document

Library of Babol university of medical science

Comments