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
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Recruitment status
Recruitment complete
Funding source
govermental

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
Babol University of Medical Sciences
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Ganj Afroz Street.babol
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Babo
Province
Mazandaran
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
Freqency 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

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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