

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the effectiveness of proton pump inhibitor (PPI) alone and with the method of adding baclofen to proton pump inhibitor (PPI) in the treatment of patients with gastroesophageal reflux disease (GERD) aged 7 to 12 years

Protocol summary

Study aim

The effect of adding baclofen to proton pump inhibitor in the treatment of patients with gastroesophageal reflux disease aged 7 to 12 years Investigating the differences in improving the quality of life of treated children in the two groups Comparison of treatment complications in the two groups Comparison of the questioned indices before and after treatment in the two groups

Design

Clinical trial is examined in two groups of patients (control-case). These two groups are 60 people, non-randomly selected in phase 4 without blinding

Settings and conduct

In this study, patients with gastroesophageal reflux disease referred to a pediatrician in the office and hospital are examined. In this study, the first group received omeprazole at a dose of 1 mg per kg body weight, the second group received omeprazole at a dose of 1 mg per kg body weight, and baclofen 0.15 mg per kg body weight, which patients were monitored. The relevant reflux standard questionnaire is completed before starting treatment and two weeks after starting treatment. Patients received treatment for 2 weeks and were evaluated for standardized indicators based on age before the intervention and two weeks after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 7-12 years with gastroesophageal reflux disease No entry conditions: Specific diseases: cerebral palsy, treated with seizure drugs , Patients with gastrointestinal ulcers and IBD

Intervention groups

Intervention group: Children 7-12 years old with gastroesophageal reflux disease who go to the office or hospital and receive baclofen and proton pump inhibitor at the same time Control group: Children 7-12 years old

with gastroesophageal reflux disease who go to the office or hospital and receive proton pump inhibitor drug

Main outcome variables

Reflux

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210308050634N1**

Registration date: **2021-06-12, 1400/03/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-12, 1400/03/22**

Update count: **0**

Registration date

2021-06-12, 1400/03/22

Registrant information

Name

Vajiheh Modaresisaryazdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3725 1830

Email address

drmodarressi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-24, 1400/03/03

Expected recruitment end date

2021-07-09, 1400/04/18

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of proton pump inhibitor (PPI) alone and with the method of adding baclofen to proton pump inhibitor (PPI) in the treatment of patients with gastroesophageal reflux disease (GERD) aged 7 to 12 years

Public title
Comparison of the effect of baclofen and proton pump inhibitors in patients with gastroesophageal reflux disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Children 7-12 years with gastroesophageal reflux disease
Exclusion criteria:
Cases of specific diseases (cerebral palsy, treated with anticonvulsant drugs, patients with gastrointestinal ulcers and IBD)

Age
From **7 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
After fully explaining the process of studying to patients and obtaining informed consent from patients, patients enter one of the treatment groups selected by the physician.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Azad University of Medical Sciences, Yazd Branch

Street address

Alem Square, Safaieh, Yazd

City

Yazd

Province

Yazd

Postal code

8915813135

Approval date

2020-06-24, 1399/04/04

Ethics committee reference number

IR.IAU.YAZD.REC.1399.033

Health conditions studied

1

Description of health condition studied

gastroesophageal reflux disease

ICD-10 code

K21

ICD-10 code description

Gastro-esophageal reflux disease

Primary outcomes

1

Description

Voice violence or difficulty speaking

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Reflux Questionnaire

2

Description

Heartburn or chest pain or sourness

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Reflux Questionnaire

3

Description

Clear the throat

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

4

Description

Coughing after eating or lying down

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Reflux Questionnaire

5

Description

Night cough

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Reflux Questionnaire

6

Description

Shortness of breath or suffocation

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Reflux Questionnaire

7

Description

Feeling of a lump in the throat that is not relieved by eating

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Reflux Questionnaire

8

Description

Sputum in the throat

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Reflux Questionnaire

9

Description

Hard swallowing of liquids and solids

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Reflux Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: An omeprazole group with a dose of 1 mg per kg body weight and baclofen 0.15 mg per kg body weight when patients are monitored. Received therapeutic intervention and were evaluated before the intervention and two weeks after the end of the intervention in terms of standardized indicators based on age.

Category

Treatment - Drugs

2

Description

Control group: In this study, omeprazole was administered to the control group at a dose of 1 mg per kg body weight and patients were monitored. The relevant reflux standard questionnaire is completed before starting treatment and two weeks after starting treatment. Patients received treatment for 2 weeks and were evaluated for standardized criteria based on age before the intervention and two weeks after the intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Social Security Hospital

Full name of responsible person

Dr. vajih Modarresi

Street address

Namaz Sq, Modarres Street, Yazd

City

Yazd

Province

Yazd

Postal code

6652565265

Phone

+98 35 3833 0756

Email

shohadakargar.hos@tamin.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Seyed Mohammadreza Mortazavizadeh

Street address

Alam Square, Safaieh, Yazd

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Yazd

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526526532

Phone

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Email

info@iauyazd.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Dr. vajih Modarresi

Position

Faculty of Islamic Azad University

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Alem Square, Safaieh, Yazd

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. vajih Modarresi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Seyedeh Maryam Bahrololoom

Position

Professional PhD student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

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

Title and more details about the data/document

The data obtained from the study will be published in the form of an article.

When the data will become available and for how long

6 to 12 months

To whom data/document is available

Everyone in medicine

Under which criteria data/document could be used

To people who study gastroesophageal reflux disease

From where data/document is obtainable

Email to the person performing the project

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

ایمیل به فرد مجری - تقاضا از معاونت پژوهشی دانشگاه- در صورت مثبت بودن آرایه اطلاعات به فرد متقاضی

Comments