Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of the effect of Esomeprazole and combination of Esomeprazole ppus Baclofen in the treatment of clinical signs of infants reflux

Protocol summary

Study aim

Evaluation of the efficacy of Esomeprazole and combination of baclofen plus Esomeprazole in the treatment of clinical symptoms of infantile reflux

Design

In this double-blind clinical trial study, 50 neonates with reflux disease were randomly divided into two groups by using Random Allocation Software. The fist group is treated with Esomprazole and the second group is treated with Es-omperazole plus Baclofen and the outcome of treatment was compared between the two groups. In this study, the patient's parents and the physician examining the patients were unaware of the type of medication received.

Settings and conduct

This study was carried out in 2020 at Hazrat Zeinab Hospital in Qom. 50 neonates with reflux were randomly divided into two groups receiving Es-omperazole and Esomperazol with Baclofen and compared the recovery status in the two groups. The study was double-blind and the parents of the patients were unaware of the type of drug being administered. The medication is also prescribed by the researcher, but the child examination and reflux treatment are performed by another pediatrician who is not in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 3 to 12 months, suffer to reflux, failure to respond to routine reflux treatments. Not inclusion criteria: history of hospitalization in neonatal intensive care unit, birth weight less than 2500, underlying disease such as cerebral palsy

Intervention groups

Patients in the first intervention group will be treated with intra capsular granules of Esomeprazole at a dose of 1 mg / kg once daily for two weeks. Patients in the second intervention group received granules intra capsular administered with Esomeprazole 1 mg / kg once daily plus baclofen 0.2 mg / kg once daily for 14 days.

Main outcome variables

Reflux, restlessness, nausea, vomiting, respiratory distress, cough, weight loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N44**
Registration date: **2020-03-16, 1398/12/26**
Registration timing: **prospective**

Last update: **2020-03-16, 1398/12/26**
Update count: **0**

Registration date

2020-03-16, 1398/12/26

Registrant information

Name
Ali Mehrabi kushki

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 31 3629 1510

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mehrabi@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-02, 1399/01/14

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of Esomeprazole and combination of Esomeprazole ppus Baclofen in the treatment of clinical signs of infants reflux

Public title

Evaluation of the efficacy of S-omeprazole alone and with baclofen in the treatment of neonatal reflux

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Range age 3 to 12 months Failure to respond to routine reflux treatments

Exclusion criteria:

History of hospitalization in neonatal intensive care unit Birth weight less than 2500 grams Having an underlying disease such as cerebral palsy

Age

From **3 months** old to **12 months** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of patients between the two intervention groups was done using random Allocation Software. In the mentioned software, the sample size is first entered into software for two groups. Then the number of study groups is entered. At the output of the software, a list of two columns is seen, with numbers 1 to 50 (total sample size) distributed in two columns randomly. Patients are divided into two groups according to the time of referral, which is the first patient number 1 and the last patient number 50.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is done by double blind method . The blinds included in this study include parents of children and person of responsible for data collection . Parents are unaware of the type of drug they are receiving.Also the drugs is prescribed by the researcher for the patients, but the outcome of the study is evaluated by another pediatrician who is unaware of the type of medication the patient is receiving.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom University of Medical Sciences

Street address

Research faculty, Qom University ofMedical Sciences, Shahi Lavasani street

City

Isfahan

Province

Isfehan

Postal code

3713649373

Approval date

2019-10-21, 1398/07/29

Ethics committee reference number

IR.MUQ.REC.1398.039

Health conditions studied

1

Description of health condition studied

Neonatal Reflux

ICD-10 code

P78.83

ICD-10 code description

Newborn esophageal reflux

Primary outcomes

1

Description

Newborn esophageal reflux

Timepoint

Before beginning intervention and the end of the first week, second week, first month, second month after intervention

Method of measurement

Investigation of clinical singes

2

Description

Restlessness

Timepoint

Before beginning intervention and the end of the first week, second week,

Method of measurement

Investigation of clinical singes

3

Description
nausea
Timepoint
Before beginning intervention and the end of the first week, second week,
Method of measurement
Investigation of clinical singes

4

Description
womitting
Timepoint
Before beginning intervention and the end of the first week, second week,
Method of measurement
Investigation of clinical singes

5

Description
respiratory distress
Timepoint
Before beginning intervention and the end of the first week, second week,
Method of measurement
Investigation of clinical singes

6

Description
cough
Timepoint
Before beginning intervention and the end of the first week, second week,
Method of measurement
Investigation of clinical singes

7

Description
weight loss
Timepoint
Before beginning intervention and the end of the first week, second week,
Method of measurement
Investigation of clinical singes

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Reflux treatment with Esomeprazole made by Rosa Darou Company as intra capsuls granules 1 mg/kg once daily for two weeks
Category
Treatment - Drugs

2

Description
Intervention group 2:Treatment of reflux with Esomeprazole as intra capsuls granules made by Roz Darou company, 1 mg / kg daily dose plus baclofen tablet (made by Roz darou company) 0.2 mg / kg once daily for 14 days:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrate Masoumeh hospital
Full name of responsible person
Leila Naderi
Street address
Imam Khomini street, Qom
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Ehsan Sharifipour
Street address
No. 83, 4 Alley, 1/1 street, Safashahr
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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

Ghoum 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

Ghoum University of Medical Sciences

Full name of responsible person

Leila Naderi

Position

Resident of pediatric

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The plan is owned by the government agency and data cannot be published.

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available