

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The comparison of the efficacy of ranitidine with esomeprazole in the recovery rate of signs and symptoms of neonatal gastro esophageal reflux disease

#### Protocol summary

##### Study aim

The comparison of the efficacy of esomeprazole with ranitidine in the treatment of GERD in term neonates.

##### Design

A randomised double blinded clinical trial with two arm parallel group and simple randomization at the individual level and using random number table with allocation concealment by sequentially numbered sealed opaque envelop.

##### Settings and conduct

The study will be conducted on 60 otherwise healthy term neonates with symptomatic GERD attending to the neonatal clinic of Bahrami Hospital. Eligible neonates will be randomly assigned to a double blind therapeutic trial in two groups receiving either ranitidine or esomeprazole. The physician who cares the patients, the researcher who collects the data and the person who analyses the data are blind.

##### Participants/Inclusion and exclusion criteria

Major Inclusion Criteria: Study subjects will include healthy and term neonates aged 1-30 days with symptoms and signs of GERD not responding to conservative therapies including anti-reflux positioning, milk thickening and hypo-allergen regimen. Major Exclusion Criteria: 1- Neonates with any underlying diseases, including anomalies or gastrointestinal obstruction, neurological diseases, sepsis, NEC, etc. 2- Using any sedative, relaxant or anticonvulsive medications. 3- History of ventilation therapy.

##### Intervention groups

Neonates who meet the criteria will be randomly assigned to two groups to receive either ranitidine 2 mg/kg /dose three times per day or esomeprazole 0.5 mg/kg / dose two times per day for one month.

##### Main outcome variables

En Primary outcome variable includes: The recovery rate in signs and symptoms of GERD. Secondary outcome

variable includes: Complications of ranitidine and esomeprazole in each group.

#### General information

##### Reason for update

##### Acronym

Neonatal GERD

##### IRCT registration information

IRCT registration number: **IRCT20160827029535N5**

Registration date: **2019-08-21, 1398/05/30**

Registration timing: **prospective**

Last update: **2019-08-21, 1398/05/30**

Update count: **0**

##### Registration date

2019-08-21, 1398/05/30

##### Registrant information

##### Name

Peymaneh Alizadeh Taheri

##### Name of organization / entity

Tehran University of Medical Sciences, Bahrami Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7301 3420

##### Email address

alizadep@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2020-03-19, 1398/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The comparison of the efficacy of ranitidine with esoprazole in the recovery rate of signs and symptoms of neonatal gastro esophageal reflux disease

---

**Public title**

The comparison of the efficacy of two therapeutic regimens in the treatment of gastroesophageal reflux disease in term neonates.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Healthy term neonates aged 1-30days with GERD .

**Exclusion criteria:**

Healthy term neonates aged 1-30days with GERD not responding to conservative therapies including antireflux positioning, milk thickening, hypoallergic regimens and monotherapy

**Age**

From **1 day** old to **30 days** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **90**

More than 1 sample in each individual

Number of samples in each individual: **1**

Each patient receives the defined drug of his group.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization at the individual level and using random number table with allocation concealment by sequentially numbered sealed opaque envelop

---

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The participants, the medical clinician, the researcher who collect data and the who analyze the data are blind.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

**Street address**

Tehran university Of Medical Sciences, Pursina Street, Ghods Av, Enghelab Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2019-06-23, 1398/04/02

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1398.251

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

Gastroesophageal Reflux

**ICD-10 code**

K21

**ICD-10 code description**

Gastro-oesophageal reflux disease

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

the comparison of ranitidine with esomeprazole in neonatal GERD

**Timepoint**

One week and one month after using each drug

**Method of measurement**

using (I-GERDQ-R) and related scoring

**Secondary outcomes****1****Description**

The side effects of each drug

**Timepoint**

After one week and one month of administering

**Method of measurement**

Clinical manifestations

## Intervention groups

1

### Description

Intervention group1: Ranitidine:2mg/kg/dose/TDS

### Category

Treatment - Drugs

2

### Description

Intervention group 2: Esomeprazole 0.5mg/kg/dose /BID

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Bahrami Hospital

#### Full name of responsible person

Peymaneh Alizadeh Taheri

#### Street address

Kiaa Ave, Damavand Ave, Imam Hossein Square

#### City

Tehran

#### Province

Tehran

#### Postal code

1641744991

#### Phone

+98 21 7756 8801

#### Fax

+98 21 7756 8809

#### Email

p.alizadet@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Bahrami hospital

#### Full name of responsible person

Peymaneh Alizadeh Taheri

#### Street address

Shahid Kiaii Street, Damavand Avenue, Imam Hossein

#### City

Tehran

#### Province

Tehran

#### Postal code

1641744991

#### Phone

+98 21 7756 8801

#### Email

p.alizadet@yahoo.com

#### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Bahrami hospital

### 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

Other

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Peymaneh Alizadeh Taheri

#### Position

Full Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Pediatrics

#### Street address

Shahid Kiaii Street, Damavand Avenue, Imam Hossein Square

#### City

Tehran

#### Province

Tehran

#### Postal code

1641744991

#### Phone

+98 73013420

#### Fax

+98 21 7756 8809

#### Email

p.alizadet@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Peymaneh Alizadeh Taheri

#### Position

Full Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Pediatrics

#### Street address

Shahid Kiaa Street, Damavand Avenue, Imam Hossein Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1641744991

**Phone**

+98 21 7301 3420

**Fax**

**Email**

p.alizadet@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Peymaneh Alizadeh Taheri

**Position**

Full Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Kiaa Ave, Damavand Ave, Imam Hossein Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1641744991

**Phone**

+98 21 7756 8801

**Email**

p.alizadet@yahoo.com

**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