

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

A clinical trial study for comparison the effects of glucose and Simeticone administration on reducing crying times in newborns with infantile colic

Protocol summary

Summary

This single center study aims to assess the relieving effects of glucose administration in neonates with infantile colic (IC). A double-blinded randomized controlled trial is designed. Seventy-six neonates who fulfill IC diagnosis (based on the Wessel criteria) are randomly assigned to one of the two groups (36 neonates per group) of daily administrated oral glucose solution (either 30% or 25%, 2.5 mg/kg) or simethicone (2.5 mg/kg) groups. Randomization is carried out by creating a random sequence of numbers using an online randomizer tool (<https://www.randomizer.org>). Neonates with systemic disorders and those who have history of receiving medication for IC are excluded. Treatments continue for 28 days. The primary and secondary outcomes are reduction in crying times and improvement of general conditions of the neonates as perceived by mothers respectively. The data is recorded using a questionnaire filling by mothers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092636423N1**

Registration date: **2017-10-28, 1396/08/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-28, 1396/08/06

Registrant information

Name

Mahvash Ebrahimi

Name of organization / entity

Zabol University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 54 3223 0764

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ebrahimimahvash@zbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy of Zabol University of Medical Sciences

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial study for comparison the effects of glucose and Simeticone administration on reducing crying times in newborns with infantile colic

Public title

The effects of glucose administration on the improvement of infantile colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of infantile colic (IC) based on the Wessel criteria; the age of 3 weeks to 6 months

Exclusion criteria: Neonates with systemic disorders; history of taking medications for IC

Age

From **21 days** old to **6 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 76

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Simethicone is administrated to the control group.

Secondary Ids

empty

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

Zabol University of Medical Sciences

Street address

Rajae street, Deputy of Education of the University,
First floor, Zabol

City

Zabol

Postal code

9861615881

Approval date

2017-06-21, 1396/03/31

Ethics committee reference number

Zbmu.1.REC..1396.95

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

Infantile colic

ICD-10 code

R10.4

ICD-10 code description

Other and unspecified abdominal pain

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

Reduction in crying times

Timepoint

One week before the initiation of the intervention, and at the end of the intervention

Method of measurement

Questionnaire filled by mothers

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

Improvement of general conditions of the neonates as perceived by mothers

Timepoint

One week before initiation of the intervention, and at the end of intervention

Method of measurement

Questionnaire filled by mothers

Intervention groups**1****Description**

Control group: Simethicone (2.5 mg/kg per day) is administrated for 28 days.

Category

Treatment - Drugs

2**Description**

Intervention group: Oral glucose is administrated as 25% or 30% solution (2.5 mg/kg per day) for 28 days.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Zabol University of Medical Sciences

Full name of responsible person

Dr Iraj Shahramian

Street address

Amir-Al-Momenin Hospital, Zabol

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Deputy of Zabol University of Medical Sciences

Full name of responsible person

Dr Iraj Shahramian

Street address

Pediatric Ward, Amir-Al-Momenin Hospital-Zabol

City

Zabol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy of Zabol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

Ali Bazi

Position

MSc

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty