

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effect of oral glucose solution for pain control during infant circumcision by ring method (Plastibell)

Protocol summary

Study aim

The effect of oral glucose solution on pain during circumcision in infants

Design

A prospective randomized controlled clinical trial, phase 3, is conducted on 60 infants who are referred for circumcision by ring insertion. Patients are randomly allocated in two groups by using of permuted block randomization.

Settings and conduct

Eligible patients referred to Kosar Hospital in Semnan will be evaluated after assigning to the intervention or control group. Before and during circumcision, the duration of crying, and the pain score based on Neonatal-Infant Pain Scale are recorded for each infant.

Participants/Inclusion and exclusion criteria

Infants, aged one to 12 months who refer for circumcision and are candidates for circumcision by inserting a ring (Plastibell) will be enrolled.

Intervention groups

In both groups, lidocaine 2% is injected at a dose of 2 mg/kg by ring block method. Then, after 3 minutes, infants in the intervention group will receive 2 cc of glucose 50% solution and control group 2cc of distilled water. Circumcision is performed 5 minutes after the onset of anesthesia.

Main outcome variables

Pain score based on Neonatal-Infant Pain Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151020024625N14**

Registration date: **2021-06-18, 1400/03/28**

Registration timing: **prospective**

Last update: **2021-06-18, 1400/03/28**

Update count: **0**

Registration date

2021-06-18, 1400/03/28

Registrant information

Name

Mehrdad Zahmatkesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3343 7844

Email address

mehrdadzahmatkesh@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral glucose solution for pain control during infant circumcision by ring method (Plastibell)

Public title

Evaluation of the effect of oral glucose solution for pain control during infant circumcision

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Infant candidate for circumcision by placing a ring (Plastibell)

Exclusion criteria:

There is not any exclusion criteria

Age

From **1 month** old to **12 months** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, a block randomization method will be used. In the study, The allocation of samples is based on a random sequence provided by a statistical expert using statistical software. The block size will be 6. Meanwhile, the tool which is used for generating random-sequence blocks is a web-based software available at <https://kitset.ir/numbers/random>.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Semnan University of Medical Sciences

Street address

Central office of Semnan University of Medical Sciences, Basidj Boulevard

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2021-02-23, 1399/12/05

Ethics committee reference number

IR.SEMUMS.REC.1399.340

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

Pain of incision site

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

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

Pain score

Timepoint

Before and during circumcision, every one minute

Method of measurement

Neonatal Infant Pain Scale

2**Description**

Duration of crying

Timepoint

Before and during circumcision.

Method of measurement

Measurement by chronometer

Secondary outcomes

empty

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

Intervention group: Lidocaine 2% is injected at a dose of 2 mg/kg by ring block method. Then, after 3 minutes, 2cc of glucose solution 50% is orally feed. Circumcision is performed 5 minutes after the onset of anesthesia.

Category

Treatment - Other

2**Description**

Control group: Lidocaine 2% is injected at a dose of 2 mg/kg by ring block method. Then, after 3 minutes, 2 cc of distilled water is orally feed. Circumcision is performed 5 minutes after the onset of anesthesia.

Category

Placebo

Recruitment centers**1****Recruitment center**

Name of recruitment center
Kowsar Hospital
Full name of responsible person
Mahshid Ghasemzadeh
Street address
Amin Avenue, Basidj Boulevard
City
Semnan
Province
Semnan
Postal code
3519899951
Phone
+98 23 3142 2021
Email
mahshid.gh1374@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Parviz Kokhaei MD
Street address
Central office of Semnan University of Medical Sciences, Basidj Boulevard
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
sem.ums.res@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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

Semnan University of Medical Sciences
Full name of responsible person
Mehrdad Zahmatkesh
Position
Researchman
Latest degree
Bachelor
Other areas of specialty/work
Epidemiology
Street address
Basidj Boulevard, Amin Ave.
City
Semnan
Province
Semnan
Postal code
3519899951
Phone
+98 23 3142 2252
Email
mehrdadzahmatkesh@semums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Setareh Soltany MD
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
Street address
Basidj Boulevard, Amin Ave.
City
Semnan
Province
Semnan
Postal code
3519899951
Phone
+98 23 3142 2120
Email
setarehsoltany@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Mehrdad Zahmatkesh
Position
Researchman
Latest degree
Bachelor
Other areas of specialty/work
Epidemiology

Street address

Basidj Boulevard, Amin Ave.

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3141 2252

Email

mehrdadzahmatkesh@semums.ac.ir

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

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

Title and more details about the data/document

Anonymised data will be offered.

When the data will become available and for how long

After publishing of final report

To whom data/document is available

Researcher who working in academic institutions

Under which criteria data/document could be used

Referees and competent people

From where data/document is obtainable

For this purpose, the applicant can send an official correspondence.

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

After verifying the applicant's position

Comments