

# 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  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Semnan University of Medical Sciences  
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Parviz Kokhaei MD  
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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  
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Epidemiology  
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## Person responsible for scientific inquiries

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**Name of organization / entity**  
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Setareh Soltany MD  
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Associate professor  
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## Person responsible for updating data

#### Contact

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**Other areas of specialty/work**  
Epidemiology

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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**

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**