Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the Effectiveness of Oral 10% Glucose solution with placebo in reducing pain due to venipuncture in Infants 1month to 1 year

Protocol summary

Study aim
Determining the effectiveness of oral 10% glucose solution on pain reduction in infants undergoing venipuncture.

Design
Hospital-based, parallel group, double-blind, Randomized Controlled Clinical Trial

Settings and conduct
This study will be conducted at the Emergency Department of Taleghani Pediatric Medical Educational Center. For this, Eligible infants (one month to one-year-old) will be recruited. After obtaining the informed consent from parents/caregivers, they will be referred to the treatment room for venipuncture with one opaque envelope containing the group code. After opening the envelope by researcher and specify the group (placebo or Glucose solution), the interested solution will be feed by parents, two minutes before venipuncture. One skilled nurse who will be blinded about the groups is responsible for doing the venipuncture for all participants. During the first try for venipuncture, a cameraman will film from the infants' face. At the end of each day, two independent persons who are blind will observe the films and determine the pain score based on the FLACC.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: age: 1month-1year Admitted at Taleghani Pediatric Medical Educational Center Candidate for Peripheral Intravenous Catheterization Excluding Criteria: Emergency Situations Suffering from life-threatening diseases

Intervention groups
Feed the Glucose solution 10%

Main outcome variables
The pain severity based on FLACC Score.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140820018883N1**
Registration date: **2018-02-21, 1396/12/02**
Registration timing: **prospective**

Last update: **2018-02-21, 1396/12/02**
Update count: **0**

Registration date
2018-02-21, 1396/12/02

Registrant information

Name
Homeira Khoddam

Name of organization / entity
Golestan university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-04, 1397/01/15

Expected recruitment end date
2018-09-21, 1397/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Oral 10% Glucose solution with placebo in reducing pain due to venipuncture in Infants 1month to 1 year

Public title
Effectiveness of Oral 10% Glucose solution in reducing pain due to venipuncture in Infants 1month to 1 year
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
age:one month to one year old Need to indwelling catheter in Limb's'peripheral veins Candidate for Intravenous Fluid Therapy Informed consent of parents to participate the Infant
Exclusion criteria:
Disturbed of consciousness Life threatening conditions (poisoning,..)
Age
From **1 month** old to **1 year** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The researcher will assign participants in two groups by using block randomization technique.
Blinding (investigator's opinion)
Double blinded
Blinding description
The infant parents/ caregiver, the nurse responsible for intravenous catheterization (health care provider) and the persons (at least two) responsible for observing records and evaluating pain severity (Outcome assessors) will be blinded. In addition, we will conceal the intervention by using coded syringes (A and B) contain simple water (Placebo) and sweet solution with the same size, shape, and brand.
Placebo
Used
Assignment
Parallel
Other design features
To prevent researchers, Healthcare provider, and parents from predicting which infant will receive which solution (Placebo or intervention), we will conceal the allocation sequence by using opaque sealed envelopes. These contain the letters A (placebo) or B (Glucose). After obtaining informed consent from parents, they will be given an envelope to take with themselves to the treatment room, where the intervention will be applied. the researcher will open the envelope and based on the letters (A or B) will assign the infants into the groups. Two minutes before intervention the solution (Placebo or Intervention) will be feed to the infants and video recording will be started.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Golestan University of Medical Sciences Research Ethical Committee.
Street address
Hircan Boulvard.
City
Gorgan
Province
Golestan
Postal code
4934174515
Approval date
2018-01-28, 1396/11/08
Ethics committee reference number
IR.GOUMS.REC.1396.268

Health conditions studied

1

Description of health condition studied
Venipuncture ãcute pain in infants admitted to Emergency Department for acute diseases
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Acute pain due to venipuncture
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain severity
Timepoint
two minutes before to two minutes after painful procedure (Venipuncture)
Method of measurement
FLACC (Face, Legs, Activity, Cry, CONSOLability) scoring system

Secondary outcomes

1

Description
Crying duration
Timepoint

from Intervention and two minute after that

Method of measurement

Observation and record by two independent observers

Intervention groups

1

Description

Intervention group: Including Eligible infants between one month and one year old admitted to Emergency Department of Hospital. They will receive 2 milliliters 10% glucose solution, one time, 2 minutes before venipuncture, orally. The researcher will draw Glucose solution into the uniform 2 milliliters syringes and will be coded(A) at the beginning of each day. The solution will be prepared by a pharmacist based on the researcher order.

Category

Prevention

2

Description

Control group: Including Eligible infants between one month and one year old admitted to Emergency Department of Hospital. They will receive 2 milliliters sterile water, one time, 2 minutes before venipuncture, orally. The researcher will draw sterile water into the uniform 2 milliliters syringes and encode(B) at the beginning of each day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Pediatric Medical Educational center

Full name of responsible person

Jabar Parhiz

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Taleghani Pediatric Medical Educational center, Janbazan BLV

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Homeira Khoddam

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Family Health

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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