Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Investigation of the effect of 2% nitroglycerin ointment - 2% lidocaine on the pain control due to intravenous catheter in infants; randomized double-blind clinical trial

Protocol summary

Study aim
Investigation of the effect of nitroglycerin-lidocaine ointment on the control of pain caused by intravenous catheter in infants

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 84 patients

Settings and conduct
After registering the proposal on the registry site http://irct.ir and obtaining permission from the ethics committee, 84 neonates under the age of one month that hospitalize in the NICU will enter the study. Patients in 2 groups will receive each topical lidocaine/nitroglycerin or placebo ointments by the permuted block method.

Participants/Inclusion and exclusion criteria
Newborns with cesarean section or non-complicated cesarean section and gestational age more than 34 weeks and postnatal age less than 4 weeks undergoing catheterization

Intervention groups
The first group: lidocaine / nitroglycerin topical combination ointment, the second group: placebo topical ointment.

Main outcome variables
pain score of catheterization, How long does the baby cry after catheterization? How long it takes for the baby to start crying, Duration of the procedure.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190810044500N19**
Registration date: **2021-08-22, 1400/05/31**
Registration timing: **prospective**
Last update: **2021-08-22, 1400/05/31**
Update count: **0**

Registration date
2021-08-22, 1400/05/31

Registrant information

Name
Fatemeh Saghafi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3820 3419

Email address
f.saghafi@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-23, 1400/06/01

Expected recruitment end date
2021-11-22, 1400/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the effect of 2% nitroglycerin ointment - 2% lidocaine on the pain control due to intravenous catheter in infants; randomized double-blind clinical trial

Public title
Evaluation of nitroglycerine and lidocaine ointment on the pain caused by catheterization in neonates

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Infants with non-complicated cesarean delivery or normal birth gestational age greater than 34 weeks and postnatal age less than 4 weeks need to intravenous catheterization

Exclusion criteria:

Parents' dissatisfaction with their baby's participation in the study

Age

From **1 day** old to **1 month** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 84 patients are randomly allocated into two treatment groups (A and B). Block randomization method will be used for random allocation. Fourteen blocks of six are considered. The generated permutations include the letters A and B, which are repeated thrice (for example, ABBABA) in each permutation. These permutations are generated using Random allocation software version 1. For this purpose, the generated list by the software is from 1 to 84, which are arranged in 14 blocks of six in order. To run this software output, we give the first qualified person number 1 and the last person will receive number 84. To consider blinding in random allocation, the list is given to another person outside the study and using short message service (SMS) before assigning the type of treatment according to the number of eligible people is asked and thus people enter the study. In addition, in the software output, both numbers 1 to 84 and the permutations of the letters A and B can be seen.

Blinding (investigator's opinion)

Double blinded

Blinding description

The steps will be covered from the perspective of the patient, the treating physician۹, and the assessors. The first presenter identifies the sequence of assignments of patients according to the order of entry of the patients into the study, and puts the ointments (combination of nitroglycerin-lidocaine or placebo) into one-size boxes for patient use, and identifies them with A or B codes. The student then delivers the drugs to each individual patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Medical School - Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Anonymous Martyrs Boulevard - Shahid Sadoughi University of Medical Sciences, Yazd

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2021-01-12, 1399/10/23

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.261

Health conditions studied

1

Description of health condition studied

Measurement of pain during catheterization in infants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain score of catheterization

Timepoint

After catheterization

Method of measurement

PIPP Score

2

Description

how long the baby cries after catheterization

Timepoint

After catheterization

Method of measurement

The duration of the baby's crying is recorded in seconds

3

Description

how long it takes for the baby to start crying

Timepoint

during catheterization

Method of measurement

The time it takes for a baby to start crying is recorded in seconds

4

Description

how long the procedure lasts

Timepoint

during catheterization

Method of measurement

The duration of the procedure is recorded in seconds

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Topical nitroglycerin ointment 2% - lidocaine 2%, one gram with an area of one square centimeter, on the infant venous site, apply and then wait for 10 minutes and then clean the site and venipuncture is performed and the amount Pain is measured.

Category

Prevention

2

Description

Control group: Placebo ointment consisting of white wax and Vaseline made by Speedro company, 1gram with an area of one square centimeter, is applied on the infant venous site, and then wait for 10 minutes, after which the site is cleansed and venipuncture is performed and the pain is measured. Placebo ointment will be made in the Pharmaceutics Laboratory of Yazd School of Pharmacy.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital, Yazd

Full name of responsible person

Zahra Ghaffarian

Street address

Ibn Sina Boulevard

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 35 3822 4000

Fax

+98 35 3822 4100

Email

sadoghi-hospital@ssu.ac.ir

Web page address

https://web.ssu.ac.ir/index.aspx?lang=1&sub=4

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mohammed Reza Mirjalili

Street address

Bahonar Square

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 1171 3724

Fax

+98 35 0371 3724

Email

ravabet@SSU.AC.IR

Grant name

Grant code / Reference number

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

No

Title of funding source

Family

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Saghafi

Position

Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmacology

Street address
Professor Hesabi Boulevard, Yazd, Iran

City
Yazd

Province
Yazd

Postal code
8915173149

Phone
+98 35 3419 3820

Email
F.saghafi@ssu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Fatemeh Saghafi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmacology

Street address
Professor Hesabi Boulevard, Yazd, Iran

City
Yazd

Province
Yazd

Postal code
8915173149

Phone
+98 35 3419 3820

Email
F.saghafi@ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Fatemeh Saghafi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmacology

Street address
Professor Hesabi Boulevard, Yazd, Iran

City
Yazd

Province
Yazd

Postal code
8915173149

Phone
0098 35 314193820

Email
F.saghafi@ssu.ac.ir

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