

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effect of local heat on the pain severity due to urine bag removal in the preterm newborns

Protocol summary

Study aim

Effect of local heat on the pain severity due to urine bag removal in the preterm newborns

Design

This is a phase 2 clinical trial study with the control group and one blinded. The groups of the study are paralleled. The sample size for each group is 30 newborns. The newborns are assigned to each group by permuted 4 randomized blocks. Randomization is performed on the following website: www.sealedenvelope.com

Settings and conduct

This study is performed on premature newborns with a gestational age of 34 to 36 weeks that is hospitalized in the neonatal intensive care of Amir-al-Momenin Hospital in Semnan, Iran. The eligible premature newborns are randomly assigned to one of the two groups of local heat and control. First, in both groups, variables of pain intensity, body temperature, heart rate, and percentage of oxygen saturation are measured before the start of the study. Then, in the intervention group, in addition to routine measures, local heat is applied to the newborn's pubic area for 5 minutes. Routine measures are also performed in the control group. Then after 5 minutes, pain intensity, temperature, pulse, and percentage of oxygen saturation will be measured again. This is a single-blinded study.

Participants/Inclusion and exclusion criteria

Premature newborns between 34 to 36 weeks of gestational age
Inclusion criteria: APGAR score higher than 7; birth weight between 2200 to 2800 gr. Exclusion criteria: Lack of consciousness of the newborn; Addiction in newborn's mother

Intervention groups

Groups of study: 1. Local heats 2. Control group

Main outcome variables

1. Pain severity due to urine bag removal 2. Body temperature 3. Heart rate 4. Spo2 saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101108005134N15**

Registration date: **2023-07-11, 1402/04/20**

Registration timing: **prospective**

Last update: **2023-07-11, 1402/04/20**

Update count: **0**

Registration date

2023-07-11, 1402/04/20

Registrant information

Name

Ali Fakhr-Movahedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4192

Email address

Alimovi49@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-16, 1402/04/25

Expected recruitment end date

2024-02-14, 1402/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of local heat on the pain severity due to urine bag removal in the preterm newborns

Public title

Effectiveness of local heat on newborns' pain

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

APGAR score higher than 7 Birth weight between 2200 to 2800 gr Newborn's parent consent

Exclusion criteria:

Lack of consciousness of the baby Congenital anomalies in newborn Addiction of newborn's mother Diabetics' mothers newborn

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After entering the study, infants are divided into the intervention and control groups based on a 4-block randomized design. The randomization unit is individual. The number of newborns is equal in each group. There isn't stratified randomization and allocation concealment. Randomization is performed by following the website: www.sealedenvelope.com

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not 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

Basij Blvd; The central headquarters of the mobilization of the Boulevard, Semnan University of medical sciences, Vice President for research and technology

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2023-05-22, 1402/03/01

Ethics committee reference number

IR.SEMUMS.REC.1402.028

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

Premature newborn

ICD-10 code

P07.3

ICD-10 code description

Preterm [premature] newborn [other]

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

Pain intensity

Timepoint

Beginning of the study, and 5 minutes after end of intervention

Method of measurement

Neonatal Infant Pain Scale

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

Heart rate

Timepoint

Beginning of the study, and 5 minutes after end of intervention

Method of measurement

Pulse oximeter

2**Description**

O2 saturation percent

Timepoint

Beginning of the study, and 5 minutes after end of intervention

Method of measurement

Pulse oximeter

3**Description**

Body temperature

Timepoint

Beginning of the study, and 5 minutes after end of intervention

Method of measurement

Digital temperature

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

Intervention group: Applying local heat using a heating pad with dimensions of 16 x 8 and a temperature of 34 to 37 degrees Celsius for 5 minutes on the pubic area. The heating pad has a cover so that the baby's skin is not damaged.

Category

Treatment - Other

2**Description**

Control group: No special action is taken in this group and it serves as a witness for the intervention group.

Category

Placebo

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

Amir -al- Momenin

Full name of responsible person

Dr. Sati Nik Darzi

Street address

Imam Hussein Square, in front of the 400 -unit apartment complex

City

Semnan

Province

Semnan

Postal code

3514734731

Phone

+98 23 3346 0066

Email

amir.hospital@semums.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Dr. Majid Mirmohammadkhani

Street address

Basij Blvd, Semnan University of Medical Sciences

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3344 1021

Email

info@semums.ac.ir

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

Ali Fakhr-Movahedi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Kilometer 5, Damghan road, Nursing and allied health faculty, Semnan university of medical sciences

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3365 4192

Fax

+98 23 3365 4192

Email

alimovi49@sem-ums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Ali Fakhr-Movahedi

Position

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Street address

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Province

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Postal code

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Phone

+98 23 3365 4192

Fax

+98 23 3365 4192

Email

alimovi@sem-ums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

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Phone

+98 23 3365 4192

Fax

+98 23 3365 4192

Email

alimovi@sem-ums.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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable