Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 commitee 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 allieh 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
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Kilometer 5, Damghan road, Nursing and allieh 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
alimovi@sem-ums.ac.ir

Person responsible for updating data

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 allieh 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
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