

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect Local Heat on Pain of Heel Prick Blood Sampling in The Term Neonates

Protocol summary

Summary

The goal of this research is investigating the local heat effects on the pain of heel blood sampling on term infants. The study's population is the infants who refer to shahid delkhah heal center of ferdows city to perform thyroid screening test. The infants with gestational age if 37 to 42 weeks, birth weight is 2500 to 4000 gr, have not been received sedation drugs the before night and awake, quite and without crying. Infants will be selected by convenient sampling. 63 infants are randomly divided into three groups: intervention, placebo and control. The stages study are: two minutes before, during and two minutes after blood sampling. heel infants in the intervention group heated by hair dryer (temperature and distance same) for three minutes before lancing. in the placebo group used only sound of hair dryer for three minutes before lancing. in the control group did not perform any intervention. in the end The pain intensity is evaluated by researcher for each of the three groups by standard scale infants (NIPS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072223299N1**

Registration date: **2015-08-17, 1394/05/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-17, 1394/05/26

Registrant information

Name

Rahimeh GHobadi

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 5027

Email address

ghobadi.r@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Gonabad University of Medical Sciences

Expected recruitment start date

2015-08-06, 1394/05/15

Expected recruitment end date

2015-10-07, 1394/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect Local Heat on Pain of Heel Prick Blood Sampling in The Term Neonates

Public title

Effect of Local Heat on Pain Control Term Infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Infants with gestational age 37 to 42 weeks: first and fifth minutes apgar score higher than 7: birth weight 2500 to 4000 gr: The age of infant is between 3 to 5 days: body temperature between 36.5 to 37.5 C: born by vaginal delivery: healthy: infants has not been received sedation drug the before night: awake: quite and without crying. Exclusion criteria: infants who for them to be used double lancet to heel for blood sampling: parents dissuasion of stay infant in this

research.

Age
From **3 days** old to **5 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **63**

Randomization (investigator's opinion)
Randomized

Randomization description

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

Gonabad University of Medical Sciences

Street address

KHorasan Razavi. Gonabad. Gonabad University of Medical Sciences

City

Gonabad

Postal code

Approval date

2015-05-31, 1394/03/10

Ethics committee reference number

IR.GMU.REC.1394.18

Health conditions studied

1

Description of health condition studied

Heel pain during sampling

ICD-10 code

M79.6

ICD-10 code description

pain in limb

Primary outcomes

1

Description

Pain

Timepoint
Two Minutes Before, During, Two Minutes After Blood Sampling

Method of measurement
Neonatal Infant Pain Scale (NIPS)

Secondary outcomes

empty

Intervention groups

1

Description

infants heel in the intervention group were exposed local heat with hairdryer (johnson model,1200 w, and distance 60 cm) for 3 minute before blood sampling.

Category

Prevention

2

Description

for Infants in the placebo group is used hairdryer voice alone, three minutes before blood sampling.

Category

Prevention

3

Description

infant in the control group has not taken intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

SHahid Delkhah Heal Center

Full name of responsible person

GHobadi Rahimeh, Graduate Student in Nursing Education, Nursing chidren

Street address

KHorasan Jonobi, Ferdows, Motahari Ave, SHahid Delkhah heal center

City

Ferdows

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabab University of Medical Sciences

Full name of responsible person

Dr Mohammadpour Ali, Research and Tecnology

Department of Gonabad University of Medical Sciences, Pr

Street address

Gonabad University of Medical Sciences

City

Gonabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabab University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

SHahid Delkhah Heal Center

Full name of responsible person

GHobadi Rahimeh

Position

Graduate Student in Nursing Education, Nursing children

Other areas of specialty/work

Street address

KHOrasan Jonobi, Ferdows, Motahari Ave, SHahid Delkhah Heal Center

City

Ferdows

Postal code

Phone

+98 56 3272 6266

Fax

Email

ghobadi.m65@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Baloochi Tahereh

Position

Graduate in Nursing Education, Professor

Other areas of specialty/work

Street address

Gonabad University of Medical Sciences

City

Gonabad

Postal code

Phone

+98 51 5722 5027

Fax

Email

tbaloochi@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

SHahid Delkhah Heal Center

Full name of responsible person

GHobadi Rahimeh

Position

Graduate Student in Nursing Education, Nursing children

Other areas of specialty/work

Street address

KHOrasan Jonobi, Ferdows, SHahid Delkhah Heal Center

City

Ferdows

Postal code

Phone

+98 56 3272 6266

Fax

Email

ghobadi.m65@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty