

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 children

##### 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

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

Baloochi Tahereh

**Position**

Graduate in Nursing Education, Professor

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## Person responsible for updating data

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**Other areas of specialty/work**

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**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*