

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The effect of warmth during intramuscular injection of vitamin K on physiological indicators and pain in term newborns

#### Protocol summary

##### Summary

The aim of this study was to determine the analgesic and physiologic effects of warmth in neonates undergoing intramuscular injection of vitamin K. Appropriate for gestational age infants of 37/1- 42 weeks of gestational age were included. Infants of mothers with substance abuse, infants of diabetic mothers, neonates with asphyxia, first and fifth minute Apgar score less than 7 were excluded. We observed the behavioral state only after the infant had spontaneously reached 1 of 3 quiet behavioral states (State 1: eyes closed, regular respiration, no movements; state 2: eyes closed, irregular respiration, small movements; or state 3: eyes open, no movements). Forty infants were divided in control and intervention groups in the first hour after birth. The protocol consisted of baseline (2 min), intervention (2 min), injection (20 s ), and recovery (2 min) periods. Infants in the intervention group were warmed by radiant warmer, first in manual mode with 100% power for 2 minutes followed by servo controlled mode with 35 degrees. Infants in the control group were also warmed by radiant warmer but only at 35 degrees in servo controlled mode during the study. Maximum heart rate and oxygen saturation were recorded two minutes before, during and two minutes after the injection in thirty-second intervals . Pain measurement were recorded independently (with NIPS scale) through video recording.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014051117645N1**

Registration date: **2014-06-07, 1393/03/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-06-07, 1393/03/17

##### Registrant information

###### Name

Behnaz Mirzaee

###### Name of organization / entity

Babol University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

behnazmirzaee61@yahoo.com

##### Recruitment status

###### Recruitment complete

##### Funding source

Babol University of Medical Sciences

##### Expected recruitment start date

2013-11-16, 1392/08/25

##### Expected recruitment end date

2013-12-16, 1392/09/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of warmth during intramuscular injection of vitamin K on physiological indicators and pain in term newborns

##### Public title

The effect of neonatal warming up on pain management and physiological indicators in term newborns

##### Purpose

Prevention

## **Inclusion/Exclusion criteria**

Inclusion criteria: infants with gestational age 37/1- 42 week with appropriate weight for gestational age; lack of palliative sedation or anti convulsion drugs during pregnancy maternal. Exclusion criteria: infants of mothers with substance abuse; infants of mothers with diabetes; neonates with asphyxia; anomalies of the face and extremities; first and fifth minute Apgar score less than 7.

### **Age**

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

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **40**

### **Randomization (investigator's opinion)**

Not 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**

Babol University of Medical Sciences

##### **Street address**

Babol University of Medical Sciences, Ganj Afroz Ave,  
Babol, Mazandaran

##### **City**

Babol

##### **Postal code**

4717641367

#### **Approval date**

2013-11-05, 1392/08/14

#### **Ethics committee reference number**

3326

## **Health conditions studied**

### 1

#### **Description of health condition studied**

The correlation of neonatal warming up infant during intramuscular injection of vitamin K with pain and

physiological indicators in term infants

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

Oxygen saturation

#### **Timepoint**

Two minutes before injection, during the injection, two minutes after injection

#### **Method of measurement**

Pulse Oximeter

### 2

#### **Description**

Pain

#### **Timepoint**

Two minutes before injection, during injection, two minutes after injection

#### **Method of measurement**

Neonatal Infant Pain Scale (NIPS)

### 3

#### **Description**

Heart rate

#### **Timepoint**

Two minutes before injection, during injection, two minutes after injection

#### **Method of measurement**

Pulse Oximeter

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Infants in the intervention group were exposed warmth in manual mode and 100% power of warmer (HKN- 93B Model) for 2 minutes during intervention phase .

#### **Category**

Prevention

### 2

#### **Description**

Infants in the control group has not taken intervention and just were exposed in servo controlled mode with 35 degrees (35 degrees) during the study.

#### **Category**

Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Ayatollah Rouhani Hospital

**Full name of responsible person**

Mirzaee Behnaz, Neonatal Intensive Care Nursing Student

**Street address**

Nursery Ward, Ayatollah Rouhani Hospital, Ganj Afrooz Ave, Babol, Mazandaran, Iran

**City**

Babol

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Zahid Pasha Ydllh

**Street address**

Research and Technology Department, Babol University of Medical Sciences, Babol, Mazandaran

**City**

Babol

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Babol 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**

Babol University of Medical Sciences

**Full name of responsible person**

Mirzaee Behnaz

**Position**

Neonatal Intensive Care Nursing Student

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Department of Education, Babol University of Medical Sciences

**Full name of responsible person**

Zahid Pasha Ydllh

**Position**

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## Person responsible for updating data

#### Contact

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**Full name of responsible person**

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## **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*