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

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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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
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Research and Technology Department, Babol University of Medical Sciences, Babol, Mazandaran
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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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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