Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Response To First-Intramuscular (IM) Injection Pain In Newborns With And Without Skin To Skin Contact

Protocol summary

Study aim

To examine the effect of skin to skin (STS) contact on first IM injection pain in newborns

Design

Randomized controlled single blind clinical trial in newborns with a sample size of 60.

Settings and conduct

Place of the study: Zeynep Kamil Hospital, Itanbul. Blinding method and process: In the intervention group, the mothers (and their babies) will not be informed about why IM injection is administered during STSC.

Participants/Inclusion and exclusion criteria

Inclusion: Literate mother, Mother aged between 18-35 years, Mother giving birth to between 37-41 weeks of gestation, Mother having no chronic disease, Mother delivering her baby in a cephalic position, Mother giving birth through vaginal delivery, Mother having no mental or psychological problem, Newborn having 1st-minute APGAR score of 7 or above, Newborn weighing 2500-4000 gr. Exclusion: Mother having breech delivery, having kiwi, vacuum and forceps-assisted delivery, Multiparous, having an APGAR score of 7 or above after any intervention, needing to be observed in the intensive care unit, having congenital anomaly, receiving oxygen treatment, rejecting skin to skin contact after birth

Intervention groups

Intervention Group: Vitamin K will be IM administered from the left leg of newborn at 6th minute after STS. The STS contact procedure will be continued after IM injection. Pain, oxygen saturation, and cardiac apex beat will be assessed in newborn before STS contact (I), at 5th minute of the contact (II), at 5th minute after injection (III) and 5 minutes after the end of STS contact (IV). Control group. STS contact will not be applied. Routine clinical practices will be continued.

Main outcome variables

Pain, Duration of crying

General information

Reason for update

We applied with the public title " The effect of postpartum skin to skin contact on the pain of first - Intramuscular injection to a newborn" However, we changed the public title to "The effect of skin to skin contact on first IM injection pain in newborns" in line with the criticism from you. But we got the institution and ethical permission with the first title we uploaded to the system. These heading differences are stated by the institutions as a problem.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200115046139N1**
Registration date: **2020-04-24, 1399/02/05**
Registration timing: **prospective**

Last update: **2020-06-24, 1399/04/04**
Update count: **1**

Registration date

2020-04-24, 1399/02/05

Registrant information

Name

Leyla Kaya

Name of organization / entity

Faculty of Health Sciences, University of Health Sciences Turkey

Country

Turkey

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-01, 1399/02/12

Expected recruitment end date

2021-05-01, 1400/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Response To First-Intramuscular (IM) Injection Pain In Newborns With And Without Skin To Skin Contact

Public title

The Effect of Postpartum Skin to Skin Contact on the Pain of First Intramuscular Injection to Newborn

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Literate mother and her newborn infant Mother aged between 18-35 years and her newborn infant Mother giving birth to between 37-41 weeks of gestation and her newborn infant Mother having no chronic disease and her newborn infant Mother delivering her baby in a cephalic position and her newborn infant Mother giving birth through vaginal delivery and her newborn infant Mother having no mental or psychological problem and her newborn infant Newborn having 1st-minute APGAR score (scoring system indicating health of newborn) of 7 or above and mother Newborn weighing 2500-4000 gr and mother

Exclusion criteria:

Mother having breech delivery and her newborn infant Mother having kiwi, vacuum and forceps-assisted delivery and her newborn infant Multiparous mother and her newborn infant Newborn having an APGAR score of 7 or above after any intervention and mother Newborn needing to be observed in the intensive care unit and mother Newborn having congenital anomaly and mother Newborn receiving oxygen treatment and mother Mother rejecting skin to skin contact after birth and her newborn infant

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be used. Newborns and their mothers will be assigned to intervention and control groups through block randomization (block size of three). MedCalc program will be used to determine order of randomization.

Blinding (investigator's opinion)

Single blinded

Blinding description

The mother and baby will not be informed about why skin-to-skin contact occurs

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Clinical Research Ethics Committee of Zeynep Kamil Women's and Children's Diseases Training and Rese

Street address

No: 10 Üsküdar; Op. Dr. Burhanettin Üstünel street

City

Istanbul

Postal code

34668

Approval date

2019-12-04, 1398/09/13

Ethics committee reference number

107

Health conditions studied

1

Description of health condition studied

Pain of First Intramuscular Injection to Newborn

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

Before the procedure, the 5th minute before the procedure, the 10th minute after the procedure, and the 15th minute after the procedure

Method of measurement

Neonatal Infant Pain Scale (NIPS)

2

Description

Crying time

Timepoint
Before the procedure, the 5th minute before the procedure, the 10th minute after the procedure, and the 15th minute after the procedure
Method of measurement
Crying time will be evaluated by timer.

Secondary outcomes

1

Description
Cardiac apex beat
Timepoint
Before the procedure, the 5th minute before the procedure, the 10th minute after the procedure, and the 15th minute after the procedure
Method of measurement
Cardiac apex beat and saturation shall be recorded through a pulse oximeter probe

2

Description
Oxygen saturation
Timepoint
Before the procedure, the 5th minute before the procedure, the 10th minute after the procedure, and the 15th minute after the procedure
Method of measurement
Oxygen saturation shall be recorded through a pulse oximeter probe

Intervention groups

1

Description
Experimental Group: When the baby is born, she/he shall be taken under the radiant heater at the mother’s room, the umbilical clamp shall be put, and the umbilical care shall be provided. After the mother and her baby wear a bracelet, the nappy shall be fastened, the baby cap shall be placed, the baby shall be covered with a preheated cover, and the STSC of the mother and her baby shall be provided. Before the mother takes the baby on her lap, the pulse oximeter probe shall be put on the right hand, and the cardiac apex beat and saturation shall be recorded through this method. Then, the NIPS (Neonatal Infant Pain Scale) shall be applied for pain assessment. The duration of crying, pain, cardiac apex beat and saturation shall be recorded before the STSC. when the baby is taken on her mother’s lap, the duration of crying, pain, cardiac apex beat and saturation shall be recorded after 5-minute STSC. Vitamin K support shall be given from the left leg, intramuscularly. After the Vitamin K support and additional 5-minute STSC, the duration of crying, pain, cardiac apex beat and saturation shall be recorded. After 10-minute STSC in total, the baby shall be taken under the radiant heater. After 5-minute observation under the radiant heater, the duration of crying, pain, cardiac apex beat and saturation shall be recorded, and the procedure shall be ended.
Category
Behavior

2

Description
Control group: When the baby is born, s/he shall be taken under the radiant heater at the mother’s room, the umbilical clamp shall be put, and the umbilical care shall be provided. After the mother and her baby wear a bracelet, the nappy shall be fastened, and the baby shall stay under the radiant heater. The pulse oximeter probe shall be put on the right hand, and the cardiac apex beat and saturation shall be recorded through this method. Then, the NIPS (Neonatal Infant Pain Scale) shall be applied for pain assessment. The duration of crying, pain, cardiac apex beat and saturation shall be recorded before STSC. After 5-minutes, Vitamin K support shall be given intramuscularly from the left leg immediately after recording of pain, cardiac apex beat and saturation. 5-minutes later, the duration of crying, pain, cardiac apex beat and saturation shall be recorded.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Zeynep Kamil Women's and Children's Diseases Training and Research Hospital
Full name of responsible person
Neriman Zengin
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Faculty of Health Sciences, University of Health Sciences
Full name of responsible person
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Grant name
none

Grant code / Reference number
none

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

Title of funding source
Faculty of Health Sciences, University of Health 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
Faculty of Health Sciences, University of Health Sciences

Full name of responsible person
Leyla Kaya

Position
Ph. D. Student of Midwifery

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Faculty of Health Sciences, University of Health Sciences

Full name of responsible person
Leyla Kaya

Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available