Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of massage on Pain Responses of Muscular Injection in Neonates

Protocol summary

Study aim
effect massage on heart rate, Oxygen saturation, pain in neonates
Design
A randomized, controlled clinical trial with a of 100 patients, enrolled between October 2018 and September 2018
Settings and conduct
Mustafa Khomeini Hospital, Gynecology ward Massage for 2 minutes was performed in intervention group and hepatitis B vaccine was injected at the same time. In the control group injection was performed without Massage
Participants/Inclusion and exclusion criteria
term neonates between 2/5-4 kg;low Apgar, Congenital Anomaly
Intervention groups
massage on pain control in experimental group no intervention on control group
Main outcome variables
pain; heart rate;Oxygen saturation

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20110420006243N3**
Registration date: **2019-07-29, 1398/05/07**
Registration timing: **retrospective**

Last update: **2019-07-29, 1398/05/07**
Update count: **0**
Registration date
2019-07-29, 1398/05/07

Registrant information
Name
Shiva Rafati
Name of organization / entity
Shahed university
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-11-22, 1397/09/01
Expected recruitment end date
2019-03-16, 1397/12/25
Actual recruitment start date
2018-12-22, 1397/10/01
Actual recruitment end date
2019-03-16, 1397/12/25
Trial completion date
2019-03-16, 1397/12/25

Scientific title
Effect of massage on Pain Responses of Muscular Injection in Neonates

Public title
massage on Pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Newborns First day
Exclusion criteria:
low apgar congenital anomaly
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: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Based on the last number of the mothers' file that were referred to this center .The Odd number were in the control group and the pair number were in the intervention group.
Blinding (investigator's opinion)
Single blinded
Blinding description
participates
Placebo
Not used
Assignment
Parallel
Other design features
The injection of hepatitis B vaccine was performed at the first four hours of birth in the quadriceps muscle. In the intervention group 2 minutes before injection, massage was performed on the site of the quadriceps muscle and simultaneously injected by the nurse. In the control group, the injection was performed by the same nurse without massage.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahed University of Medical Sciences
Street address
Mustafa Khomeini hospital,Italia street
City
Tehran
Province
Tehran
Postal code
3319118651
Approval date
2018-12-24, 1397/10/03
Ethics committee reference number
IR.SHAHED.REC.1397.090

Health conditions studied

1

Description of health condition studied
pain
ICD-10 code
R52.0
ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
pain according to Neonatal infant scale pain
Timepoint
before injection, during injection, 5 minutes after injection
Method of measurement
NIPS scale item

Secondary outcomes

1

Description
heart rate
Timepoint
before injection, during injection, 5 minutes after injection
Method of measurement
pulse oxymeter

Intervention groups

1

Description
Intervention group 1: two minutes of direct rhythmic Effleurage massage on the quadriceps muscle by the same person and injection hepatitis B vaccine at the same time by the same nurse
Category
Treatment - Other

2

Description
Control group:injection hepatitis B vaccine by the same nurse without any additional work
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mustafa Khomeini Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Dr Kiasalari
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persian Gulf Hwy/Tehran - Qom
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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
Ardabil University of Medical 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
Shahed University
Full name of responsible person
Shiva Rafati
Position
Assistant Professor
Latest degree
Specialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
all of data are shared after annomyons
When the data will become available and for how long
12 months after publishing
To whom data/document is available
researchers in universities
Under which criteria data/document could be used
without limitation
From where data/document is obtainable
rafati@shahed.ac.ir
What processes are involved for a request to access data/document
1 month
Comments