

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effect of massage versus no massage on pain responses of blood sampling in infant: a randomized clinical trial

Protocol summary

Summary

The aim of this study is to determine the effect of massage versus no massage on pain responses of infants during blood sampling. Design: This is a single-blind randomized controlled clinical trial. This study was conducted on 136 infants within 3 days of birth; affected with hyperbilirubinemia (icter); without congenital anomalies and chromosomal diseases; hospitalized in Mostafa Khomeini hospital affiliated to Shahed University. Infants were randomly studied once as experiment and once as control by using random number tables (68 infants in groups). Researcher assessed the pain responses caused by blood sampling in infants. Physiological (Blood pressure; Respiratory rate; Pulse rate; Oxygen saturation) and behavioral responses of pain (Scale NIPS) were assessed. We assessed pulse rate : blood pressure : respiratory rate:and oxygen saturation level as physiological responses and we assessed facial expressions (which were measured by neonatal facial coding system) as behavioral responses. In the intervention group massage was used from 1 minute before blood sampling. At any time (experience or control) recording was done two minutes before sampling, after blood sampling and 5 minutes after sampling. Researchers who measure the outcomes of the study subjects are not aware of what the intervention has received by each participant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412127529N7**
Registration date: **2015-01-11, 1393/10/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-11, 1393/10/21

Registrant information

Name

Nahid Rejeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 3071

Email address

reje@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahed University Vice chancellor for research

Expected recruitment start date

2014-10-07, 1393/07/15

Expected recruitment end date

2015-02-04, 1393/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of massage versus no massage on pain responses of blood sampling in infant: a randomized clinical trial

Public title

Effect of massage on pain responses of blood sampling in infant

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: gestational age infant between 37-42

weeks; birth weight between 2500 - 4000 gr ; Apgar score above 7 at 5 minutes; within 3 days of birth; ; affected with hyperbilirubinemia (icter);without congenital anomalies and chromosomal diseases ; neurological diseases; cardiologic or respiratory impairments, infection diseases, and metabolic diseases; any other painful intervention such as circumcision and injection. Exclusion criteria: Now the bad baby such as undergoing of mechanical ventilation or need to sedative;, the first needling for blood sampling was not successful; receiving sedatives or analgesics for 24 hours before the procedure; addicted mothers; drugs and antidepressants during pregnancy ; With experience endotracheal intubation and CPR; unwillingness the parents for complete the study;

Age

From **3 days** old to **30 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **136**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Infants were randomly studied once as experiment and once as control by using random number tables .
Researchers who measure the outcomes of the study subjects are not aware of what the intervention has received by each participant.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way Tehran, Iran

City

Tehran

Postal code

Approval date

2014-11-22, 1393/09/01

Ethics committee reference number

41/215588

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Pain

Timepoint

two minutes prior to sampling, after inserting needle and five minutes after removing the need

Method of measurement

Neonatal Infant Pain Scale(NIPS)

2

Description

Blood pressure

Timepoint

two minutes prior to sampling, after inserting needle and five minuet after removing the need

Method of measurement

phygmomanometer

3

Description

Respiratory rate

Timepoint

two minutes prior to sampling, after inserting needle and five minuet after removing the need

Method of measurement

Checklist

4

Description

Pulse rate

Timepoint

two minutes prior to sampling, after inserting needle and five minuet after removing the need

Method of measurement

Checklist

5

Description

Oxygen saturation

Timepoint

two minutes prior to sampling, after inserting needle and five minuet after removing the need

Method of measurement

pulse oximeter

Secondary outcomes

empty

Intervention groups**1****Description**

In intervention group, massage is done 1 minutes before vein puncture in antecubital local

Category

Other

2**Description**

In Control group: no intervention

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mostafa Khomini Hospital in Tehran

Full name of responsible person

Dr. Shiva Rafati

Street address

Mostafa Khomini Hospital; Italia street; Tehran; Iran.

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahed University Vice chancellor for research

Full name of responsible person

Dr. Zahra Kiasalari

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way Tehran Tehran Iran

City

Tehran

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

Yes

Title of funding source

Shahed University Vice chancellor for research

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**

Shahed University

Full name of responsible person

Dr. Shiva Rafati

Position

Assistant Professor

Other areas of specialty/work**Street address**

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way Tehran, Iran

City

Tehran

Postal code**Phone**

00

Fax**Email**

nrejah@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Associate Professor

Other areas of specialty/work**Street address**

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way Tehran, Iran

City

Tehran

Postal code**Phone**

+98 212151210

Fax**Email**

nrejah@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Associate Professor

Other areas of specialty/work**Street address**

Shahed University, Opposite to Holy Shrine of Imam
Khomeini, Tehran-Qom Express way , Tehran ,Iran

City

Tehran

Postal code**Phone**

00

Fax**Email****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