

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8896 9437

##### Email address

rafati@shahed.ac.ir

##### 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

Shiva Rafati

##### Street address

Mustafa Khomeini Hospital,Italia street

##### City

Tehran

##### Province

Tehran  
**Postal code**  
14116643491  
**Phone**  
+98 21 8896 3122  
**Email**  
rafati@shahed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Ardabil University of Medical Sciences  
**Full name of responsible person**  
Dr Kiasalari  
**Street address**  
persian Gulf Hwy/Tehran - Qom  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
3319118651  
**Phone**  
+98 21 5121 5105  
**Email**  
info@shahed.ac.ir  
**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  
**Other areas of specialty/work**  
Pediatrics  
**Street address**

Mostafa khomeini hospital,Italia street  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1416643491  
**Phone**  
+98 21 8896 9437  
**Fax**  
+98 21 8896 3122  
**Email**  
rafati@shahed.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Shahed University  
**Full name of responsible person**  
Shiva Rafati  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Mostafa khomeini hospital,Italia street  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1416643491  
**Phone**  
+98 21 8896 9437  
**Fax**  
+98 21 8896 3122  
**Email**  
rafati@shahed.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Shahed University  
**Full name of responsible person**  
Shiva Rafati  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Mostafa khomeini hospital,Italia street  
**City**  
Tehran  
**Province**  
Tehran

**Postal code**

1416643491

**Phone**

+98 21 8896 9437

**Fax**

+98 21 8896 3122

**Email**

rafati@shahed.ac.ir

## 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**