

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Effect of Swedish Massage Versus Touch on pain during venipuncture in school age children in pediatric emergency department

#### Protocol summary

##### Summary

The purpose of the study was to investigate the effect of Swedish Massage Versus Touch on pain during venipuncture in school age children in pediatric emergency department. Eligible criteria school age children (children ages 12-6 years old; willingness to cooperate in investigation; Lack acute pain during venipuncture; consciousness of time and place and person; Lack of narcotic addiction; Lack of cardiovascular disorders) that participants will selected using convenience sampling method and randomly divided into three groups (Swedish Massage, Touch and control). In intervention groups for 5 minutes intervention is done and immediately venipuncture is performed by nurse colleagues. In the control group, no specific action. Exclusion criteria: Resistance versus massage and touch; Having threatening emergency; Burns or damage skin in limb). Outcome: Effect of Swedish Massage Versus Touch on pain during venipuncture.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013053013524N1**

Registration date: **2014-02-23, 1392/12/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-02-23, 1392/12/04

##### Registrant information

##### Name

Ali Safari

##### Name of organization / entity

Mashhad Faculty Of Nursing and Midwifery

##### Country

Iran (Islamic Republic of)

##### Phone

+98 915 710 7561

##### Email address

safaria901@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Council of Mashhad University of Medical Sciences

##### Expected recruitment start date

2013-09-19, 1392/06/28

##### Expected recruitment end date

2013-11-19, 1392/08/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Swedish Massage Versus Touch on pain during venipuncture in school age children in pediatric emergency department

##### Public title

Effect of Swedish Massage Versus Touch on pain during venipuncture

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion Criteria: willingness to cooperate in the investigation; children ages 12-6 years old; Lack acute pain during venipuncture; Skillful nurses in venipuncture, that confirmed the child as a person that more likely can take in first attempt his/her veins in the site; consciousness of time and place and person; Lack of mental retardation; Lack of narcotic addiction; Lack of

mask and no neurological damage such as facial nerve palsy; Lack of cardiovascular disorders; Lack of hypoxia; Lack of problem for massage and touch on skin surface (such as sore, burns on hands, infections, fraction of limb, etc); Lack of take effective medication on pain in 24 hours before venipuncture; Participation at least one parent or a member of family; Require hospitalization and intravenous line with prescription their physician; Lack of contraindications for massage, such as fever, thrombophlebitis, thrombocitopeni, edema, hypertension. Exclusion criteria: Failure in venipuncture first attempt; Resistance versus massage and touch; Having threatening emergency (shock, cardiac arrhythmia, etc); Burns or damage skin in limb; Lack of would to continue cooperation working in project.

#### Age

From **6 years** old to **12 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **90**

#### Randomization (investigator's opinion)

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

Ethics Committee Of Mashhad University Of Medical Sciences

##### Street address

Building Qureshi, Daneshgah Street, Mashhad.

##### City

Mashhad

##### Postal code

#### Approval date

2013-08-17, 1392/05/26

#### Ethics committee reference number

research/920160/1/110

## Health conditions studied

### 1

#### Description of health condition studied

lack of special illness

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Intensity venipuncture pain

#### Timepoint

During intervention and period of 30 seconds to 300 seconds

#### Method of measurement

Faces pain scale

## Secondary outcomes

### 1

#### Description

Pain during venipuncture

#### Timepoint

During intervention and period of 30 seconds to 300 seconds

#### Method of measurement

Faces pain scale

## Intervention groups

### 1

#### Description

Hand and arm of venipuncture site in Swedish Massage group Massage is given for 5 minutes Immediately before venipuncture.

#### Category

Prevention

### 2

#### Description

Hand and arm of venipuncture site in touch group touch is given for 5 minutes immediately before venipuncture

#### Category

Prevention

### 3

#### Description

In the control group, no specific action

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Ali Safari

**Street address**

Avenue Ibn Sina, Imam Reza Square, Mashhad

**City**

Mashhad

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**Email**safaria901@mums.ac.ir, alis201146@gmail.com,  
alis201146@yahoo.com**Web page address**<http://www.mums.ac.ir/nurse/fa/index>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice Chancellor for Research, Mashhad University of  
Medical Sciences**Full name of responsible person**

Mohsen Tafaghodi

**Street address**Faculty of Nursing and Midwifery, Ebn-e Sina St,  
Doktora Crossing**City**

Mashhad

**Grant name**

گرانت پژوهشی

**Grant code / Reference number**

research/920160/1/110

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

Yes

**Title of funding source**Vice Chancellor for Research, Mashhad 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****Contact****Name of organization / entity**

Mashhad Faculty of Nursing and Midwifery

**Full name of responsible person**

Ali Safari

**Position**

MS Nursing/Postgraduate Student

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

Ebn-e Sina St, Doktora Crossing

**City**

Mashhad

**Postal code**

9681654469

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

Mashhad Faculty of Nursing and Midwifery

**Full name of responsible person**

Hamidreza Behnam Vashani

**Position**

Master of Science in Nursing

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

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behnamhr@mums.ac.ir

**Web page address**<http://www.mums.ac.ir/nurse/fa/index>**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad Faculty of Nursing and Midwifery

**Full name of responsible person**

Ali Safari

**Position**

MS Nursing/Postgraduate Student

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alis201146@yahoo.com**Web page address**<http://www.mums.ac.ir/nurse/fa/index>

## **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*