

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effect of massage and breastfeeding on response to pain due to venipuncture among hospitalized neonates in NICUs of selected hospitals of Esfahan University of Medical Sciences 2012.

Protocol summary

Summary

Among hospitalized neonates in NICUs of selected hospitals of Esfahan University of Medical Sciences 2012. Background: Untreated procedural pain, lead to long-term and short-term complications in neonates. The role of nurses in pain management and reduce this complications is very important and essential. Preventing of pain in sick and acute neonates, not only is legal duty, but also decreases psychological and even neurological complications in the future. So, it is essential for nurses to prevent or treat pain in neonates. The aim of this study is to compare effects of massage and breast milk on pain of the neonates. Aim: to compare the effect of massage and breastfeeding on response to pain due to venipuncture among hospitalized neonates in NICUs of selected hospitals of Esfahan University of Medical Sciences. Objectives: 1- Determine and compare the mean venipuncture pain score, between massage and control groups. 2- Determine and compare the mean venipuncture pain score, between massage and breastfeeding groups. 3- Determine and compare the mean venipuncture pain score, between breastfeeding and control groups. 4- Determine and compare the mean venipuncture pain score, between breastfeeding and massage and control groups. Implications for practice: Suggestion of using an effective and suitable non-pharmacological way for reduce venipuncture pain, in order to provides a simple, low cost alternative intervention in reduce venipuncture pain. Study questions: 1- What is the mean venipuncture pain in massage group? 2-What is the mean venipuncture pain in breastfeeding group? 3- What is the mean venipuncture pain in control group? Hypothesis: 1- Mean pain score is deferent in massage and breastfeeding groups. Mean pain score in breastfeeding group is higher than control group. Method and statistical analyses: This was a quasi-experimental study with 75 term& near term

infants requiring a venipuncture were studied. Infants were randomly allocated to one of the following treatment groups: group 1, breastfeeding (n = 25); group 2, massage (n= 25); group 3, control (n = 25). In the first group (breastfed group), mothers were asked to be in a comfort position and take their infants in their arms and feed them with their milk. Venipuncture was done two minutes after breastfeeding. In the 2nd group (massage), neonates received massage for 3 minutes and Venipuncture was done two minutes after massage. The Neonatal Infant Pain Scale (NIPS) used for measurement of pain score at the first 30 seconds of venipuncture. Data analyzed with SPSS software using t-test and one-way analysis of variance.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013020212346N1**

Registration date: **2013-06-10, 1392/03/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-06-10, 1392/03/20

Registrant information

Name

Azamolmolouk Elsagh

Name of organization / entity

Isfahan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2964

Email address

a_elsagh@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Science

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of massage and breastfeeding on response to pain due to venipuncture among hospitalized neonates in NICUs of selected hospitals of Esfahan University of Medical Sciences 2012.

Public title

The effect of massage in reduce pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: being awake; term or near term; gestational age more than 34 Weeks; no problem for breast feeding; having experience of breast feeding; no signs of cerebral palsy or chromosomal disorder and asphyxia and no crying before venipuncture. Exclusion criterion: aspiration or apnea that make study impossible.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 75

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

N/A

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezar Jarib Ave- Isfahan

City

Isfahan

Postal code

8174673461

Approval date

2012-10-10, 1391/07/19

Ethics committee reference number

391294

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R07.2

ICD-10 code description

Precordial pain

Primary outcomes

1

Description

Pain

Timepoint

Before and during doing venipuncture

Method of measurement

NIPS Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1 breast feeding : the sample breastfed for 5 minutes before sampling. When BF become completed, neonate lying supine position on the examination table.

Category

Prevention

2

Description

Control group: the neonates lying on the examination table without intervention.

Category

Prevention

3

Description

Massage group: the sample was lying on the examination table and receive eflorage technique of massage by researcher hand's for 5 minutes before venipuncture.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Azahra Hos

Full name of responsible person

Zargham-Boroujeni, Ali,

Street address

Isfahan- Hezarjarib Ave- Nursing and Midwifery Care Research Center, Faculty of Nursing and Midwifery

City

Isfahan

2

Recruitment center

Name of recruitment center

Shahid Beheshti Hos

Full name of responsible person

DR zargham

Street address

Isfahan- Hezarjarib Ave- Nursing and Midwifery Care Research Center, Faculty of Nursing and Midwifery

City

Isfahan

3

Recruitment center

Name of recruitment center

Amiralmomenin Hos

Full name of responsible person

DR zargham

Street address

Shahreza- Pasdaran Ave

City

Shahreza

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University Medical Science- vice chancellor for research, faculty of Nursing and Miwifery

Full name of responsible person

Maryam Kianpour

Street address

Hezarjarib Ave

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University Medical Science- vice chancellor for research, faculty of Nursing and Miwifery

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

Isfahan University of Medical Sciences

Full name of responsible person

Dr Ali Zargham. Broujeni

Position

MSc, PhD. Assistant Professor

Other areas of specialty/work

Street address

Isfahan University Of Medical Science - Hezarjarib Avenue

City

Isfahan

Postal code

8174673461

Phone

+98 31 1792 2964

Fax

Email

zargham@nm.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr Ali Zargham. Broujeni

Position

MSC, PhD. Assistant Professor

Other areas of specialty/work

Street address

Isfahan University Of Medical Science - Hezarjarib Avenue

City

Isfahan
Postal code
8174673461
Phone
+98 79 22964
Fax
Email
azargham@gmail.com
Web page address

Postal code
86149-56113
Phone
+98 32 1222 9055
Fax
Email
azamolmolouk@yahoo.com; a_elsagh@nm.mui.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Azamolmolouk Elsagh
Position
MSC student.NeonatalIntensive careNursing student
Other areas of specialty/work
Street address
No 33- 24 Ave- Amirkabir St.
City
Shahreza

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