Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of the effect of hand reflexology on pain, anxiety and hemodynamic parameters in children who are candidates for surgery during Insertion of the Intravenous (IV) Catheter

Protocol summary

Study aim

The effect of hand reflexology on pain, hemodynamic exercises in children undergoing surgery during intravenous line

Design

The present study is a double blind randomized clinical trial with two intervention and control groups. The number of 88 children eligible for the study were entered into the study using the available method and were randomly divided into two groups of reflexology and control using the block method (blocks of four and with an allocation ratio of 1:1 using a random table).

Settings and conduct

Subjects will be divided into two equal control and intervention groups using block randomization method. Reflexology will be performed for 5 minutes before placing the intravenous line in the intervention group. Two trained nurses will measure pain intensity, anxiety and hemodynamic parameters independently. This study will be conducted in the hospitals of Qom University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: 3-6 year old children with full consciousness and physiological stability Not having mental disability Decreased sensitivity to pain caused by any other disease No use of painkillers, sedatives, corticosteroids or relaxants Hospitalization for the first time Absence of pain during sampling Exclusion criteria: Inability to place an IV line in the first step and the child's non-cooperation during the implementation of interventions

Intervention groups

In order to perform the intervention in the intervention group, the researcher will perform a massage on the skin of the hand with slow stroking movements with moderate pressure of the palm five minutes before taking the vein and during insertion. In the control group, the establishment of the venous route will be done without intervention and based on the department's routine

Main outcome variables

Pain, hemodynamic parameters remain stable

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221205056718N2**
Registration date: **2023-02-04, 1401/11/15**
Registration timing: **prospective**

Last update: **2023-02-04, 1401/11/15**
Update count: **0**

Registration date

2023-02-04, 1401/11/15

Registrant information

Name

Hossein Sharafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3197 1087

Email address

hsharafi@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study of the effect of hand reflexology on pain, anxiety and hemodynamic parameters in children who are candidates for surgery during Insertion of the Intravenous (IV) Catheter

Public title
The effect of hand reflexology on pain, anxiety and hemodynamic parameters
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
3-6 year old children Full consciousness Physiological stability Not having mental disability Decreased sensitivity to pain caused by any other disease No use of painkillers, sedatives, corticosteroids or relaxants Hospitalization for the first time Absence of pain during sampling
Exclusion criteria:
Inability to place an IV line in the first attempt Child's non-cooperation during interventions
Age
From **3 years** old to **6 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
children who are eligible for the study are entered into the study using the available method and are randomly assigned to two intervention and control groups using the block method (blocks of four and with an allocation ratio of 1:1 using a random number table).
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the participants will not know about the study due to their young age, and only the child's parents will know. Also, if the child refuses touch and reflexology, he will be excluded from the study. Two nurses who complete the evaluation questionnaires. And the data analyst will not know about the control and intervention groups. After the intervention, the two nurse assessors will enter the operating room and evaluate the child at the designated times.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Qom University of Medical Sciences
Street address
No. 83, Safashehr St., Shahid Lotfi Niaser- Shahid Lotfi Niaser Alley, Safashehr Street, Qom
City
Qom
Province
Ghoum
Postal code
93456-37169
Approval date
2023-01-30, 1401/11/10
Ethics committee reference number
IR.MUQ.REC.1401.227

Health conditions studied

1

Description of health condition studied
anxiety
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
Pain related to Reflexology
Timepoint
Before, immediately and 5 minutes after the intervention
Method of measurement
Face, Legs, Activity, Cry, Consolability scale

2

Description
Anxiety related to Reflexology
Timepoint
Before, immediately and 5 minutes after the intervention

Method of measurement
Modified Yale Preoperative Anxiety Scale

Secondary outcomes

1

Description
Hemodynamic parameters
Timepoint
Before, immediately and 5 minutes after the intervention
Method of measurement
Digital heart monitoring system

Intervention groups

1

Description
Intervention group: Different parts of the hands and arms, with special attention to the areas related to the central nervous system, pituitary gland, spine, solar plexus and head reflexes of patients. For example, the middle of the thumb, which is related to the pituitary reflex, and the side that is related to the spinal reflex. This will be done using a sliding thumb motion, pressing and moving in each area
Category
Treatment - Other

2

Description
Control group: In the control group, the venous route will be established without intervention and based on the routine of the department. The variables in the control group will be measured as before in the intervention group, immediately after vein extraction and 5 minutes after placing the venous catheter by the same two nurses.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Qom Shahid Beheshti Hospita
Full name of responsible person
Majid Moghadam
Street address
Qom - Shahid Beheshti Blvd.
City
Qom
Province
Ghoum
Postal code
3719964797
Phone
+98 25 3612 2824
Fax
+98 25 3612 2855
Email
bmc@muq.ac.ir
Web page address
https://bmc.muq.ac.ir/

2

Recruitment center
Name of recruitment center
Khyerin Salamat educational research and therapeutic complex
Full name of responsible person
Javad Hakim Elahi
Street address
Qom - Shahid Del Azar St
City
Qom
Province
Ghoum
Postal code
7335537158
Phone
+98 25 3721 1061
Email
Nekoeihospital@muq.ac.ir
Web page address
https://nekuei.muq.ac.ir/

3

Recruitment center
Name of recruitment center
Qom Kamkar-Arabnia Hospital
Full name of responsible person
Dr. Seyed Alireza Chavoshizadeh
Street address
Qom . 19th Street (Bajek)
City
Qom
Province
Ghoum
Postal code
3713614975
Phone
+98 25 3718 5000
Email
h_sharafi68@yahoo.com
Web page address
https://kamkar.muq.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Mehdi Mesri
Street address

Qom - Shahid Lavasani St. (Saheli) - Qom University of Medical Sciences and Healthcare Services

City
Qom

Province
Ghoum

Postal code
3713649373

Phone
+98 25 3107 1111

Email
hsharafi@muq.ac.ir

Web page address
https://muq.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Ghoum 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
Ghoum University of Medical Sciences

Full name of responsible person
Hossein Sharafi

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Qom University of Medical Sciences ,pardisan

City
Qom

Province
Ghoum

Postal code
3749153434

Phone
009892531971087

Email
h_sharafi68@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Hossein Sharafi

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Pardisan,Qom University of Medical Sciences

City
Qom

Province
Ghoum

Postal code
3749153434

Phone
+98 25 3197 1087

Email
h_sharafi68@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Hossein Sharafi

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Pardisan.Qom University of Medical Sciences

City
Qom

Province
Ghoum

Postal code
3749153434

Phone
+98 25 3197 1087

Email
h_sharafi68@yahoo.com

Web page address

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

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The second half of 2023

To whom data/document is available

There is no restriction on access to the results

Under which criteria data/document could be used

There are no restrictions after de-identifying people

From where data/document is obtainable

hossein sharafi tell:00989173596990 email: h_sharafi68@yahoo.com hsharafi@muq.ac.ir

What processes are involved for a request to access data/document

The request for the data that is irrefutably identified will be made through the e-mail introduced by the researcher, and the request will be reviewed in less than 10 days and the requested data will be provided to the requester.

Comments