

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of distraction on pain intensity and physiological indicators before orthopedic surgery in children

Protocol summary

Study aim

The aim of this study was to determine the effect of distraction on pain intensity and physiological indicators before orthopedic surgery in children.

Design

Double blind, randomized clinical trial, with control group, with a parallel group design of 60 children under orthopedic surgery.

Settings and conduct

This study will be performed in the surgical ward of Shafa Yahyaian Hospital in Tehran. In the experimental group, the bubble maker game will be used to create a distraction, during which the researcher and the child will make bubbles using the bubble maker game. The game lasts for 10 minutes. In the control group, patients will receive only routine care without any additional intervention. Patients will be assigned to two groups randomly and blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Fracture for the first time, having at least a pain score of 4 on the scale of pain behavioral scale, age between 3-6 years, no hearing and vision problems and retardation, having a diagnosis of closed supracondylar fractures of the humerus, not receiving analgesics Up to 3 hours before the intervention. Exclusion criteria: lack of pain, unwillingness to continue participating in the research, inability to continue participating in the research, restlessness of the child and intolerance of research conditions.

Intervention groups

This study will be performed on two groups of experimental, including distraction (play therapy) and control including routine interventions.

Main outcome variables

Pain intensity and physiological indicators before orthopedic surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120109008665N13**

Registration date: **2021-04-05, 1400/01/16**

Registration timing: **prospective**

Last update: **2021-04-05, 1400/01/16**

Update count: **0**

Registration date

2021-04-05, 1400/01/16

Registrant information

Name

Hassan Babamohamadi

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4190

Email address

babamohamadi@sem-ums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of distraction on pain intensity and physiological indicators before orthopedic surgery in children

Public title

The effect of distraction on pain intensity and physiological indicators before orthopedic surgery in children

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

No history of hospitalization No underlying disease
Getting a fracture for the first time Awareness of time, place and person Have a minimum pain score of 4 on the pain behavioral scale Age between 3-6 years Lack of hearing and vision problems and retardation Diagnosis of supracondylar closed fractures of the humerus Lack of receive analgesic for up to 3 hours before the intervention

Exclusion criteria:

No pain Illness and inability to continue participating in research Child restlessness and intolerance to research conditions Reluctance to continue participating in research

Age

From **3 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be assigned randomly to the experimental and control groups using the Random Block method. In this method, A represents the experimental group, and B represents the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are randomly assigned to groups using double random blocks containing letters A and B, each identifies the experimental or control groups. Participants, the outcome assessor, and the data analyst are unaware of the allocation of individuals to experimental and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences

Street address

Vice Chancellor of Research and Technology, Semnan University of Medical Sciences, Basidj Blv, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3519899951

Approval date

2021-03-09, 1399/12/19

Ethics committee reference number

IR.SEMUMS.REC.1400.007

Health conditions studied

1

Description of health condition studied

Acute pain due to fracture

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

Primary outcomes

1

Description

The severity of the pain

Timepoint

Before the intervention (game), immediately after the game and ten minutes after it

Method of measurement

Pain-induced behavioral reactions scale (Face, Legs, Activity, Cry, Consolability)

Secondary outcomes

1

Description

Physiologic indicators (Systolic BP, Diastolic BP, Mean arterial pressure, and Pulse)

Timepoint

Before the intervention (game), immediately after the game and ten minutes after it

Method of measurement

Saadat Portable monitor for the pediatric ward of Shafa

Intervention groups

1

Description

Intervention group: In order to perform the intervention in the experimental group, after sufficient explanations about the study objectives and work method, during the introduction and establishing a trusting relationship, written consent will be obtained from the parents of children who meet the inclusion criteria. Then the pain and physiological indicators are measured before the intervention and the game begins in the presence of the parents. In this study, the bubble maker game will be used to create a distraction, during which the researcher and the child will make bubbles using the bubble maker game. The game lasts for 10 minutes. Pain and physiological indicators are also measured immediately after the game and ten minutes after it is done.

Category

Behavior

2

Description

Control group: In the control group, patients will receive only routine care without any additional intervention. Evaluations and measurements will be performed at the beginning of the study, 10 minutes and 20 minutes later.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Yahyaian Educational and Clinical Centre

Full name of responsible person

Hassan Babamohamadi

Street address

Shafa Yahyaian Educational and Clinical Centre,
Mojahedin-e-Islam St, Baharestan Square

City

Tehran

Province

Tehran

Postal code

3513138111

Phone

+98 21 3354 2001

Email

babamohammady2007@gmail.com

Web page address

<https://shafa.iuums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

Street address

Semnan University of Medical Sciences, Vice
Chancellor of Research and Technology, Basidj Blv,
Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3345 1336

Email

rds@semums.ac.ir

Web page address

<http://rtvc.semums.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Hassan Babamohamadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery Faculty, Semnan University of
Medical Sciences, 5 Kilometers of Damghan Road,
Semnan, Iran

City

Semnan

Province

Semnan

Postal code
3513138111
Phone
+98 23 3365 4192
Fax
+98 23 3365 4209
Email
babamohammady2007@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Hassan Babamohamadi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nursing and Midwifery Faculty, Semnan University of
Medical Sciences, 5 Kilometers of Damghan Road,
Semnan, Iran
City
Semnan
Province
Semnan
Postal code
3513138111
Phone
+98 23 3365 4192
Fax
+98 23 3365 4209
Email
babamohammady2007@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Hassan Babamohamadi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nursing and Midwifery Faculty, Semnan University of
Medical Sciences, 5 Kilometers of Damghan Road,
Semnan, Iran
City
Semnan
Province
Semnan
Postal code
3513138111
Phone
+98 23 3365 4192
Fax
+98 23 3365 4209
Email
babamohammady2007@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available