

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effect of pre-operative face-to-face education on pain and anxiety of children with upper or lower extremities trauma undergoing outpatient surgery

Protocol summary

Summary

Aim:The effect of face to face training in pain severity and anxiety in children with outpatient surgery 2-**Plan:** After getting permission from Dezful University of Medical Sciences and submitting it to the President of Dr. Ganjavian Hospital of Dezful and the Head of the Emergency Department,30,6 to 12year-old children who need outpatient surgery with local anesthesia in all parts except for their faces and those who have inclusion criteria have been selected within two months. 3-**Method:**The patients in this study have been divided into two intervening and control groups based on the date day (couple & single). Oral and written letters of satisfaction from parents will recive. 4-Inclusion criteria: patient's consciousness; lack of mental and anxiety disorders; the avoidance of taking tranquilizers and painkillers before surgery. Exclusion criteria: the need for using tranquilizers and painkillers during and at the end of surgery; parents' unwillingness to continue cooperating 5-Interventions: The method and principles of wound care have been described for the patients in the intervening group in a simple language. Moreover, the children have been informed that they can have a faster surgery if they cooperate. In both groups, it has been recommended that the parents accompany their children during the surgery. 6-Original variables:The anxiety and pain level of children was measured using Modified-Yale Preoperative Anxiety Scale (M-YPAS) and Faces Pain Scale-Revised (FPS-R)respectively in 3 stages: preoperative and pre-intervention (baseline), preoperative and post-intervention, and postoperative and post-intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020714930N4**

Registration date: **2016-04-17, 1395/01/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-17, 1395/01/29

Registrant information

Name

Marzieh Beigom Bigdeli Shamloo

Name of organization / entity

Dezful Medical Sciences University

Country

Iran (Islamic Republic of)

Phone

+98 61 4252 3912

Email address

m.bigdeli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Dezful Medical Sciences University

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pre-operative face-to-face education on pain

and anxiety of children with upper or lower extremities trauma undergoing outpatient surgery

Public title
The Effect of Education on severity of pain and anexity

Purpose
Supportive

Inclusion/Exclusion criteria
nclusion criteria:age between 6 and 12 years old, lack of any sign of bone fractures, dislocation, amputation, presence of a foreign body, nerve damage, fever as well as infection, not using cast or splint at trauma site, having full consciousness and being able to understand and follow instructions to complete pain and anxiety assessment scales, children being accompanied by their parents (either mother or father) on the day of admission, speaking Persian (both children and their parents being able to speak and read Persian), lack of using sedative or analgesic before the surgery, lack of developmental, physical or psychological problems, not having previous hospitalization, emergency department admission or surgery after 18 months of age, and lack of having a long-term illness and/or pain that requires special medical care. Children who their parents disagreed to continue the study were excluded

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

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **84**

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
Etics Committe of Dezful Medical Sciences University
Street address
Dezful Medical Sciences University, the end of Azadegan Bol
City

Dezful
Postal code
Approval date
2016-02-01, 1394/11/12
Ethics committee reference number
IR.DUMS.REC.14

Health conditions studied

1

Description of health condition studied

pain
ICD-10 code
R52.0
ICD-10 code description
Acute pain

2

Description of health condition studied

anexity
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
pain
Timepoint
before,during and 1 hour after the end of surgery
Method of measurement
Faces Pain Scale-Revised (FPS-R)

Secondary outcomes

1

Description
anexity
Timepoint
before,during and 1 hour after the end of surgery
Method of measurement
Modified-Yale Preoperative Anxiety Scale (M-YPAS)

Intervention groups

1

Description
wound care have been described for the patients in the intervening group in a simple language.
Category
Other

2

Description

Control group: No training

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Ganjavian Hospital

Full name of responsible person

Marzieh Beigom Bigdeli Shamloo

Street address

Dr Ganjavian Hospital, Dezful_ Andimeshk road

City

Dezful

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research Dezful Medical Sciences University

Full name of responsible person

Malihe Sohrabi Vafa

Street address

Dezful University of Medical Sciences , the end of Azadegan Bol

City

Dezful

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research Dezful Medical Sciences University

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

Dezful Medicine Sciences University

Full name of responsible person

Marzieh Beigom Bigdeli Shamloo

Position

Mastery degree of education nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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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