

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Investigation of the effect of intravenous catheterization and infusion orientation used by illustration on anxiety of hospitalized school-aged children in pediatric Emergency Department

Protocol summary

Registration timing: **registered_while_recruiting**

Summary

The aim of this study is to determine the effects of intravenous catheterization and infusion orientation used by illustration on anxiety of hospitalized school-aged children in pediatric Emergency Department of Shohadaye Khalije Fars Hospital. This experimental research is a clinical trial in which 112 children ages 6-12 years are randomly brought into either intervention or control groups. orientation is implemented through illustration by means of a booklet in which the procedure has been demonstrated fluently. After being visited by the doctor, the child accompanied by either parent will be entered the treatment room. Followed by 3 minutes waiting in the room, the child will be oriented by the procedure through the graphical booklet along with verbal explanation, if he belongs to the intervention group. But if he is in control group, the orientation will be limited to just verbal explanation (intervention phase) and then the procedure will be continued, both by the same nurse. Presence or absence of the 8 operational distress behavior mentioned in Observational Scale of Behavioral Distress (OSBD) will be recorded by the trained observer during the procedure at each phase and scored based on distress intensity. This study is divided into 4 phases in which the orientation will be executed between phases 1 and 2. Phase 1: attending in waiting room for 3 minutes; Phase 2: positioning injection site and skin cleaning; Phase 3: intravenous catheterization and infusion procedure execution; Phase 4: from the end of phase 3 to 3 minutes after that.

Last update:

Update count: **0**

Registration date

2017-05-29, 1396/03/08

Registrant information

Name

Faezeh Jahanpour

Name of organization / entity

Bushehr University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Bushehr University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of intravenous catheterization and infusion orientation used by illustration on anxiety of

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041712830N22**

Registration date: **2017-05-29, 1396/03/08**

hospitalized school-aged children in pediatric Emergency Department

Public title

The effect of intravenous catheterization and infusion orientation used by illustration on anxiety of children.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: • 6-12 years old; • Informed Parental consent; • Child assentation to participate in the research; • first day of admit and first hospitalization; • Child being accompany by either parent; Exclusion criteria: • Taking analgesic and anxiolytic drugs (at least 6 hours before procedure); • Taking another nonpharmacological pain management method during procedure; • Failure in first catheterization; • Children with physical problems (verbal, mental, sight, hearing) • Unconsciousness; • Known psychological illnesses suffering; • Needing for emergency vascular access.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **112**

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 Bushehr University of Medical Sciences

Street address

No. 12, Bahmani, Yasini Avenue, Bushehr University of Medical Sciences Campus, Bushehr, Iran

City

Bushehr

Postal code

Approval date

2017-04-17, 1396/01/28

Ethics committee reference number

IR.BPUMS.REC.1395.1

Health conditions studied

1

Description of health condition studied

Generalized anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Child anxiety

Timepoint

At each phase

Method of measurement

Observational Scale of Behavioral Distress

Secondary outcomes

empty

Intervention groups

1

Description

Control group: intravenous catheterization and infusion orientation by means of verbal explanation

Category

Behavior

2

Description

intravenous catheterization and infusion orientation by means of graphical booklet

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Khalije Fars Hospital

Full name of responsible person

Street address

City

Boushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,bushehr University of
Medical Sciences

Full name of responsible person

Afshin Ostavar

Street address

NO 12, Campus of Medical Sciences,Bahamni, Yasini
Avenue, Bushehr

City

Bushehr

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,bushehr 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**

Bushehr University of Medical Sciences

Full name of responsible person

Faeze Jahanpoor

Position

PhD in Nursing / Associate Professor

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

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Web page address

Person responsible for updating data

Contact

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