Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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 excecution; Phase 4: from the end of phase 3 to 3 minutes after that.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041712830N22**

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

Registration timing: **registered_while_recruiting**

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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Phone

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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

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
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Position
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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