Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Reviews the impact of the wind down the balloon on the amount of pain when venous blood ¬ dial in children admitted to the children's section

Protocol summary

Summary

This study will be carried out in 2016 with the aim to determine the effect of inflating the balloon on the amount of pain during intravenous blood sampling for children 4-7 years old hospitalized in pediatric ward of Imam Khomeini Hospital Jiroft. A study (single-blind for both intervention and control groups due to lack of awareness of any group from the existence of the other group) on 80 children admitted to the pediatric ward who have the inclusion conditions will be done after obtaining personal consent from parents. Children will be placed randomly in one of the intervention group (n = 40) and control group (n = 40) that in the intervention group, pediatric pain during intravenous blood sampling will be measured at the same time with inflating balloon and in the control group, only pediatric pain during blood collection will be measured without any intervention. For pain assessment, Wong-Baker FACES Pain Rating Scale (WBS) will be used.

General information

Acronym

NOT

IRCT registration information

IRCT registration number: **IRCT2016111329817N2**

Registration date: **2017-02-11, 1395/11/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-11, 1395/11/23

Registrant information

Name

Esmat Nuhi

Name of organization / entity

Kerman University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5220

Email address

e_nuhi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

NOT

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Reviews the impact of the wind down the balloon on the amount of pain when venous blood ¬ dial in children admitted to the children's section

Public title

The impact of the wind down the balloon on the amount of pain when venous blood ¬ dial

Purpose

Supportive

Inclusion/Exclusion criteria

(Inclusion criteria: children 4-7 years; written informed consent to participate in the study by parents, lack of known hypersensitivity to plastic materials in children, the lack of a specific disease in children (thyroid disorders, epilepsy and cardiovascular diseases and children hyperactivity), lack of disease or specific medication use that may result in lowering of

consciousness. Exclusion criteria: children who visit more than once for blood sampling; children who do not clear vessel; children who have a history of hospitalization).

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
NOT

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences

Street address
Kerman, the beginning of tCampus University of Medical Sciences, beginning around seven gardens Alavi, Kermanhe boulevard Haft Bagh Alavi, Medical Sciences Campus

City
Kerman

Postal code
--

Approval date
2016-10-16, 1395/07/25

Ethics committee reference number
IR.Kmu.REC.1395.260

Health conditions studied

1

Description of health condition studied
pain in childraen

ICD-10 code
--

ICD-10 code description
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Primary outcomes

1

Description
pain

Timepoint
Before and after intervention

Method of measurement
The questionnaire Wong-Bakker

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, a balloon is given to children and asked them to inflate it all the time of blood sampling (up to 10 seconds).

Category
Other

2

Description
In the control group, just blood sampling is done with no intervention.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital in Jiroft County

Full name of responsible person
Dr. Esmat Nouhi

Street address
Imam Khomeini hospital، Hospital intersection، Imam Boulevard، Jiroft

City
Jiroft

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Deputy of Kerman university of Medical Sciences

Full name of responsible person
Dr.Abbas Pardakhty

Street address

Kerman, Tahmasebabad Crossroads, St. Ibn Sina, Campus University of Medical Sciences, beginning around seven gardens Alavi, Kerman

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy of Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Dr. Esmat Nouhi

Position

PhD

Other areas of specialty/work

Street address

Kerman, the beginning of the boulevard Haft Bagh Alavi, Medical Sciences Campus

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Person responsible for updating data

Contact

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Web page address

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