

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

An Evaluation of effect of Balloon Inflation and distractions on self report pain and behavior reactions of venipuncture in 4-7 year children

Protocol summary

Summary

Objective: study of comparative effect of balloon inflation and distraction techniques on intravenous catheter pain among 4-7 years old children. Methods: 90 child [balloon group (30), distraction group (30) and control group (30)] were selected by using available random sampling from 4-7 years old children community admitted in Ghods hospital of Qazvin, Iran in 1387. Questionnaire of this study included three sections: demographic, Wong-Baker (FACES) Pain Rating Scale and scale of reactions and behaviors caused by pain FLACC (Face Legs Arms Cry Consolability Scale). In Balloon and distraction group, before injection we talked with child and trained them how to inflate balloon and press a rubber ball. During intravenous catheter using tools, the level of pain was determined, but in the control group without any intervention intravenous catheter was injected and then the level of pain for this group was determined; and ultimately the rate of pain in the three groups were compared together using inferential statistics.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808182688N1**

Registration date: **2008-06-26, 1387/04/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2008-06-26, 1387/04/06

Registrant information

Name

Tahereh Sadeghi

Name of organization / entity

Qazvin University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Qazvin university of medical sciences

Expected recruitment start date

2008-06-26, 1387/04/06

Expected recruitment end date

2008-09-29, 1387/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An Evaluation of effect of Balloon Inflation and distractions on self report pain and behavior reactions of venipuncture in 4-7 year children

Public title

Effect of balloon inflation and distraction techniques on intravenous catheter pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1-Age of 4-7 years and need to intravenous catheter, 2-Before injecting intravenous catheter, Wong-Baker FACES Pain Rating Scale should be zero. Exclusion criteria: 1-no history of hospitalization, 2- no history of injection of intravenous catheter, 3- not to use any particular drug, (drugs that affect on child's consciousness), 3-no Specific diseases (such as

hypothyroidism, epilepsy and cardiovascular disease...),
4- acute disease that decreases child consciousness.

Age

From **4 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin university of medical sciences

Street address

Qazvin, Shahid Bahonar Blvd

City

Qzvin

Postal code

Approval date

empty

Ethics committee reference number

1429

Health conditions studied

1

Description of health condition studied

Acute pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

pain

Timepoint

before and after the venipuncture

Method of measurement

Pain Assessment Scale

Secondary outcomes

1

Description

Complication of pain control

Timepoint

during Venipuncture

Method of measurement

Pain Assessment Scale

Intervention groups

1

Description

distraction during injection

Category

Treatment - Other

2

Description

balloon inflation during injection

Category

Treatment - Other

3

Description

no intervention in control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods hospital

Full name of responsible person

Tahereh Sadeghi

Street address

Qods Square

City

Qzvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Akram Shahrokhi

Street address

Shahid Bahonar Blvd

City

Qazvin

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Tahereh Sadeghi

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Position**Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email****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*