Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of doll injection display on the intensity of anxiety and pain due to intramuscular injection in pre-schoo children

Protocol summary

Summary
The present research is on the effect of doll injection display on the intensity of anxiety and pain due to intramuscular injection in pre-school children. The present study is a clinical experimental and double blind. The research sample consists of 50 children suffering pharyngitis that aged 4-6 years old and need intramuscular injection of penicillin 6.3.3. The participants were randomly divided into two groups (experimental group and one control group). The instruments used in the research include: demographic Information questionnaire, the Scale of facial self-report of anxiety and pain questionnaire Usher. Before intramuscular injection on the samples in the experimental group, intramuscular injection was done on a doll by a nurse. Anxiety of patients before and after the intervention and pain was measured after intervention. The analysis of the data was carried out through SPSS.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT2015070623103N1**
Registration date: **2015-07-26, 1394/05/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2015-07-26, 1394/05/04

Registrant information
Name
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Gonabad University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Gonabad University of Medical Sciences

Expected recruitment start date
2015-03-10, 1393/12/19
Expected recruitment end date
2015-06-21, 1394/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of doll injection display on the intensity of anxiety and pain due to intramuscular injection in pre-schoo children

Public title
The effect of doll injection on pain and anxiety of children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: children 4 to 6 years old; parental consent to participate in research; accompanied by a parent; children with pharyngitis disease following injections of the drug as directed by physician groups have penicillin; no intramuscular injection in the last week; lack of acute and chronic pain due to other factors in the body; lack of physical disability; lack of chronic disease; not taking medications that reduce anxiety; taking medications that reduce pain; is able to communicate Exclusion criterion: patient not cooperate

with the therapist.

Age
From **4 years** old to **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Gonabad University of Medical Sciences

Street address
Gonabad University of Medical Sciences, Almahdi St.

City
Gonabad

Postal code
9691793718

Approval date
2015-03-10, 1393/12/19

Ethics committee reference number
IR.GMU.REC.1394.19

Health conditions studied

1

Description of health condition studied
Pharyngitis

ICD-10 code
J02,9

ICD-10 code description
Pharyngitis, Acute or NOS

Primary outcomes

1

Description
Pain

Timepoint
After intervention

Method of measurement
Oucher questionnaire

2

Description
Anxiety

Timepoint
Before and after the intervention.

Method of measurement
Self-report questionnaire Piyeri

Secondary outcomes

1

Description
Age

Timepoint
Before intervention

Method of measurement
Questionnaire

2

Description
Gender

Timepoint
Before intervention

Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group; in this group before Intramuscular injection of penicillin 6.3.3 on the child, once intramuscular injection (similar to the actual injection) is done on the doll and the child will see this action, then intramuscular injection is done on the child.

Category
Other

2

Description
Control group; in this group intramuscular injection of penicillin 6.3.3 routinely is done on the child.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center Health Network Khalil Abad

Full name of responsible person
Mr. Khazaee

Street address
Imam Khomeini St.

City
Khalil Abad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Mohammad Reza Ghadimi

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Gonabad University of Medical Sciences, Almahdi St.

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Grant name

Grant code / Reference number

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

Title of funding source
Gonabad 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
Gonabad University of Medical Sciences

Full name of responsible person
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PhD Environmental Health / Management Education

Other areas of specialty/work

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Person responsible for scientific inquiries

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Master's Degree in Nursing

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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