

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

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

Iran (Islamic Republic of)

Phone

+98 51 5523 2395

Email address

zivari.m@gmu.ac.ir

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

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

Mostafa Zivari

Name of organization / entity

Gonabad University of Medical Sciences

Country

Scientific title

The effect of doll injection display on the intensity of anxiety and pain due to intramuscular injection in pre-school 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. Khazaei
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
Street address
Gonabad University of Medical Sciences, Almahdi St.
City
Gonabad

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
Dr. Mojtaba Afsharnya
Position
PhD Environmental Health / Management Education
Other areas of specialty/work
Street address
Gonabad University of Medical Sciences, Almahdi St.
City
Gonabad
Postal code
9691793718
Phone
+98 51 5722 5080
Fax
+98 51 5722 3814
Email
WWW.GMU.AC.IR

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Irani Hassan
Position
Master's Degree in Nursing
Other areas of specialty/work
Street address
Gonabad University of Medical Sciences, Almahdi St.
City
Gonabad
Postal code
9691793718
Phone
+98 51 5722 5080
Fax
+98 51 5722 3814
Email
www.gmu.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Mostafa Zivari
Position
MSc Nursing
Other areas of specialty/work
Street address
Gonabad University of Medical Sciences, Almahdi St.
City
Gonabad
Postal code
9691793718
Phone
+98 51 5722 5080
Fax
+98 51 5772 7315
Email
zivari.m@gmu.ac.ir
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