Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison effect of two methods of distraction with playing dough and bubbles making on Pain Intensity during venipuncture in 3-6 age children in pediatric emergency department and parental satisfaction

Protocol summary

Summary

The aim of this study is comparing the effect of playing dough and bubbles making on pain intensity during venipuncture in children and parental satisfaction. Inclusion Criteria: informed consent for participation in the study; children who have been admitted for the first time; presence of a parent; lack of any visible growth retardation and inability; lack of chronic diseases; lack of severe pain before intervention; aged between 3-6 years; lack of narcotic addiction; lack of taking narcotic analgesics drugs, sedatives and analgesics drugs in 24 hours before venipuncture; lack of history of previous hospitalization and venipuncture. Exclusion Criteria: discard from continuance of the study for any reason; severe pain during the intervention. This study is a randomized clinical trial with three- groups of 90 children 3-6 years old referring to pediatric emergency department of Ghaem and Dr Sheikh and Imam Reza hospitals of Mashhad. Sampling was conducted via convenience sampling method and participants randomly divided into three groups (play dough group, bubble blowing group and control). Then the children who were in play dough group were encouraged by the help of researcher to play dough and make figures five minutes before venipuncture to the end of venipuncture process, and also the bubble blowing group children were persuaded to bubble blowing just 5 minutes before venipuncture to the end of it. The Control group received the warden common procedure. Each of the three mentioned groups were asked to announce the level of their pain using Wong-Baker (FACES) Pain Rating Scale 10 minutes after the venipuncture procedure. In addition, the parental satisfactions, were measured by the researcher-made questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030621349N1**
Registration date: **2015-06-03, 1394/03/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-03, 1394/03/13

Registrant information

Name

zahra sajjadi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 58 3722 9666

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2015-03-30, 1394/01/10

Expected recruitment end date

2015-05-31, 1394/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison effect of two methods of distraction with playing dough and bubbles making on Pain Intensity during venipuncture in 3-6 age children in pediatric emergency department and parental satisfaction

Public title
Effect of distraction on Pain during venipuncture
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion Criteria: informed consent for participation in the study; children who have been admitted for the first time; presence of a parent; lack of any visible growth retardation and inability; lack of chronic diseases; lack of severe pain before intervention; aged between 3-6 years; lack of narcotic addiction; lack of taken of narcotic analgesics drugs, sedatives and analgesics drugs in 24 hours before venipuncture; lack of history of previous hospitalization and venipuncture. Exclusion Criteria: discard from continuance of the study for any reason; severe pain during the intervention.
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: **90**
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 of Mashhad University of Medical Sciences
Street address
Mashhad Faculty of Nursing and Midwifery,Ebn-e Sina St, Doktora Crossing, Daneshgah Ave.
City
Mashhad
Postal code
Approval date
2015-02-23, 1393/12/04
Ethics committee reference number
research/930949/1/372

Health conditions studied

1

Description of health condition studied
pain
ICD-10 code
R52.0
ICD-10 code description
Acute Pain

Primary outcomes

1

Description
Pain Intensity during venipuncture
Timepoint
10 minutes after the venipuncture
Method of measurement
by using the Wong-Baker (FACES) Pain Rating Scale

Secondary outcomes

1

Description
Parental satisfaction
Timepoint
After the venipuncture
Method of measurement
Researcher-made questionnaire

Intervention groups

1

Description
The children who were in play dough group were encouraged by the help of researcher to play dough and make figures five minutes before venipuncture to the end of venipuncture process.
Category
Behavior

2

Description
The bubble blowing group children were persuaded to bubble blowing just 5 minutes before venipuncture to the end of it. .
Category
Behavior

3

Description
The Control group received the warden common procedure (talking a nurse with the child to calm her during venipuncture).
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatric Emergency Department , Dr Shaikh Hospital, Mashhad University of Medical Sciences
Full name of responsible person
Shahrokh Maghsoudi
Street address
Mashhad Faculty of Nursing and Midwifery,Ebn-e Sina St, Doktora Crossing.
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2

Recruitment center
Name of recruitment center
Pediatric Emergency Department,Ghaem Hospital, Mashhad University of Medical Sciences
Full name of responsible person
Shahrokh Maghsoudi
Street address
Mashhad Faculty of Nursing and Midwifery,Ebn-e Sina St, Doktora Crossing.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Dr.Mohsen Tafaghodi
Street address
Building Qureshi,Ebn-e Sina St, Mashhad
City
Mashhad
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, Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Zahra Sajjadi
Position
Master of Science student in pediatric Nursing
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Person responsible for scientific inquiries

Contact
Name of organization / entity
School of Nursing and Midwifery, Mashhad
Full name of responsible person
Shahrokh Maghsoudi
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Master of Science in Nursing,Faculty member of School of Nursing and Midwifery, Mashhad
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Person responsible for updating data

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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