

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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

##### Email address

sajjadiz921@mums.ac.ir

##### 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.

###### City

Mashhad

#### 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.

###### City

Mashhad

### 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

##### Other areas of specialty/work

##### Street address

Mashhad Faculty of Nursing and Midwifery, Ebn-e Sina  
St, Doktora Crossing.

##### City

Mashhad

##### Postal code

##### Phone

+98 58 3722 9666

##### Fax

##### Email

SajjadiZ921@mums.ac.ir

##### Web page address

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

School of Nursing and Midwifery, Mashhad

##### Full name of responsible person

Shahrokh Maghsoudi

##### Position

Master of Science in Nursing, Faculty member of

School of Nursing and Midwifery, Mashhad

##### Other areas of specialty/work

##### Street address

Mashhad Faculty of Nursing and Midwifery, Ebn-e Sina  
St, Doktora Crossing.

##### City

Mashhad

##### Postal code

##### Phone

+98 58 3722 9666

##### Fax

##### Email

MaghsoudiSh@mums.ac.ir

##### Web page address

### Person responsible for updating data

#### 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

**Other areas of specialty/work****Street address**

Mashhad Faculty of Nursing and Midwifery, Ebn-e Sina  
St, Doktora Crossing.

**City**

Mashhad

**Postal code****Phone**

+98 58 3722 9666

**Fax****Email**

sajjadiz921@mums.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*