

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### The effect of play on young children pain during burn wound care

#### Protocol summary

##### Summary

A randomized clinical trial is proposed for investigating the effect of playing with toys on the severity of pain during burn dressing change in 3-6 year-old children presenting to Shahid Motahari Burns Hospital for their first burn dressing change. After obtaining the ethics approval for conducting the study, 78 children are placed in control and intervention groups. The FLACC scale is used in both groups to measure the severity of pain before and during the dressing (upon removing the previous dressing) and the arterial blood oxygen level and pulse are then measured by a pulse oximeter. In the intervention group, the child learns about the dressing steps 15 minutes before starting the procedure using a doll that has burns and with the help of the child who uses toy dressing to dress the doll; the child gets to keep the doll as his own dressing begins. In the control group, dressing is performed as is the routine. The data pertaining to pain, pulse and arterial blood oxygen level are recorded in both groups before and during dressing and are then compared. To achieve a blinded study, a research assistant performs the observations and records the data. The measured pain, pulse and arterial blood oxygen level are ultimately compared between the control and intervention groups. Each child receives a gift at the end of the dressing. Informed consents will be obtained from the parents of all the participants.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201602281788N15**

Registration date: **2016-05-06, 1395/02/17**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-06, 1395/02/17

#### Registrant information

##### Name

Leili Borimnejad

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6150 4212

##### Email address

borimnej@iums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Center for Nursing Research Iran University of Medical Sciences

#### Expected recruitment start date

2016-03-10, 1394/12/20

#### Expected recruitment end date

2016-06-09, 1395/03/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of play on young children pain during burn wound care

#### Public title

The effect of play on young children pain during burn wound care

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion : Girls and boys: aged 3-6 years old: no auditory or visual impairment, no mental retardation: capable of establishing verbal communication: no pain except the burn pain: receiving no painkillers. Exclusion: Burns with

chemicals, electricity or bitumen: burn in the perineum, head or neck area

### 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: **78**

### 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

Iran University Of Medical Sciences

##### Street address

Shahid Hemmat Highway, Tehran

##### City

Tehran

##### Postal code

#### Approval date

2016-01-23, 1394/11/03

#### Ethics committee reference number

IR.IUMS.REC.1394.9311687009

## Health conditions studied

### 1

#### Description of health condition studied

Burn

#### ICD-10 code

T29.2

#### ICD-10 code description

Burns of multiple regions, no more than second-degree burns mentioned

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Before intervention, at the end of intervention

#### Method of measurement

Scale flacc

## Secondary outcomes

### 1

#### Description

Pulse

#### Timepoint

Before and After Dressing

#### Method of measurement

Pulse oximetry

### 2

#### Description

Arterial Oxygen Saturation

#### Timepoint

Before and After Dressing

#### Method of measurement

Pulse oximetry

## Intervention groups

### 1

#### Description

Dressing steps are taught to the child 15 minutes before they start dressing in the intervention group, a doll with a burn, which is finally given to the child, is first dressed using toy dressing with the help of children themselves. Then the children's dressing is performed.

#### Category

Behavior

### 2

#### Description

The dressing is performed routinely in the control group.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hospital martyr Motahhari Iran University of Medical Sciences and Health

##### Full name of responsible person

Atefeh Mosavi

##### Street address

Rashid Yasami St, Vanak square, Valiasr St, Tehran, Iran

**City**  
Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Research Center School of Nursing and Midwifer

**Full name of responsible person**  
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Favulty of Nursing and Midwifery, Rashid Yasami st.  
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**Grant name**  
94-05-28-27314

**Grant code / Reference number**  
94-05-28-27314

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

Yes

**Title of funding source**  
Research Center School of Nursing and Midwifer

**Proportion provided by this source**

**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*

### 2

#### Sponsor

**Name of organization / entity**  
Research Center School of Nursing and Midwifer

**Full name of responsible person**  
Sedighe Khanjari

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Tehran

**Grant name**  
**Grant code / Reference number**

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

Yes

**Title of funding source**  
Research Center School of Nursing and Midwifer

**Proportion provided by this source**

**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

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Iran University of Medical Sciences

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PHD/ Assistant Training

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## Person responsible for scientific inquiries

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**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*