

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

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Name of organization / entity

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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

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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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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
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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
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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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