

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The Effect of Distraction Technique on the Pain of Dressing Change in 3-6 Year-old Children

Protocol summary

Summary

The present study is a single-blind RCT study which aims to determine the effect of distraction on the intensity of second grade burn dressing change in 3-6 year-old children will be admitted to Zareh hospital in 2015. The research environment is Zareh hospital burn unit. The study population consisted of all children suffering from 2nd degree burns that treatment will be in the burn unit of Zareh hospital. Samples selected by available sampling and 3-6 year-old children were assigned to control group and distraction group by random sampling based on the table of random numbers. For the experimental group, 3 minutes before the dressing [18], distraction started by displaying a game on a portable monitor and continued until the end of dressing change and in the control group, dressing change will be done without any intervention. One of the parents will be attended during the procedure in both groups. Data collection tools in this study will be demographic and medical information questionnaires (Gender, age, weight, percentage of body burns and the burned organ) and behavioral pain scale for children (Flacc scale).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111425029N1**

Registration date: **2016-03-06, 1394/12/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-06, 1394/12/16

Registrant information

Name

Sima Kaheni

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy of Research, Mazandaran University of Medical Sciences

Expected recruitment start date

2015-12-01, 1394/09/10

Expected recruitment end date

2016-01-30, 1394/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Distraction Technique on the Pain of Dressing Change in 3-6 Year-old Children

Public title

The effect of Distraction Technique on pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria were the age of child (beginning of third year to the end of sixth year); 2nd degree burns; 9-35% body surface burns; alertness to place; time and person; having the ability to communicate; non-verbal and auditory disorders; absence of acute and chronic

diseases; and the presence of a parent with the child. In the event of a life-threatening emergency, samples excluded from the study.

Age

To **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences,sari,Iran

City

sari

Postal code

4816715793

Approval date

2015-12-13, 1394/09/22

Ethics committee reference number

IR.MAZUMS.REC.94-1410-

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T32.3

ICD-10 code description

Corrosions involving 30-39% of body surface

Primary outcomes

1

Description

pain

Timepoint

Before and during the intervention

Method of measurement

Flacc scale

Secondary outcomes

empty

Intervention groups

1

Description

For The intervention group of 3 minutes before the dressing change, distraction using a portable monitor through a game show for children will continue till the end of the dressing change.

Category

Other

2

Description

in the control group, dressing change will be done without any intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

zarea Martyr Hospital

Full name of responsible person

sima kaheni

Street address

zarea Martyr Hospital, Taleghani Blvd, Sari, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

Street address

Ahmad Ali Enayat ,Deputy of Research and Technology,Moallem Field,Sari, Iran ,

City

Sari

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences, faculty of nursing and medwifery Sari, Iran

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Position
master degree/Faculty member

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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