Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 questionaires (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

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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

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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

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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

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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