

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the Effect of Vision and Auditory Distractions on Physiologic Indicators and Pain of Dressing change in 6-12 Years Old Children at the Burn Center of Besat Hospital, 1397-98.

Protocol summary

Study aim

Comparison of the Effect of Vision and Auditory Distractions on Physiologic Indicators and Pain of Dressing change in 6-12 Years Old Children at the Burn Center of Besat Hospital.

Design

A total of 120 hospitalized children in the burning ward with available sampling will be selected from patients' files and then by randomized block assignment placed in a 3 groups clinical trial control, auditory distraction and visual distraction.

Settings and conduct

When changing dressing on the basis of self-reported pain scale, pain is noted for each patient by the researcher. 20 minutes before and 10 minutes after dressing, the physiological indexes of the units of study, including heart rate and arterial oxygen saturation, will be measured in each of the three control groups, visual distortion and auditory deviation, and recorded in special sheets. At the moment of changing the dressing, and then at intervals every two minutes until the end of the dressing, the physiological indicators are measured and recorded in special sheets, then the mean will be obtained and reported.

Participants/Inclusion and exclusion criteria

Lack of speech impairment and mental retardation, No burns in the eyes and ears, The level of burn is 35-9% and grade 2 in the body based on the doctor's diagnosis

Intervention groups

play animation In the first intervention group, the audio tracks of the Ministry of Culture and Guidance for children, in the second intervention group, non-intervention in control group

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170117032025N4**

Registration date: **2019-01-27, 1397/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-27, 1397/11/07**

Update count: **0**

Registration date

2019-01-27, 1397/11/07

Registrant information

Name

Arash Khalili

Name of organization / entity

Hamadan University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0320

Email address

a.khalili@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-04-04, 1398/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Vision and Auditory Distractions on Physiologic Indicators and Pain of Dressing change in 6-12 Years Old Children at the Burn Center of Besat Hospital, 1397-98.

Public title

the Effect of Vision and Auditory Distractions on Physiologic Indicators and Pain of Dressing change in 6-12 Years

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The level of burn is 35-9% and grade 2 in the body based on the doctor's diagnosis Age 6-12 Years Old

Exclusion criteria:

burns in the eyes and ears speech impairment and mental retardation

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Available sampling from patients' files and then randomized block assignment in a 3 groups clinical trial control, auditory distraction and visual distraction.

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 Hamadan University of Medical Sciences

Street address

Shahid Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

6561058582

Approval date

2018-11-17, 1397/08/26

Ethics committee reference number

IR.UMSHA.REC.1397.565

Health conditions studied

1

Description of health condition studied

burn

ICD-10 code

T31

ICD-10 code description

Burns classified according to extent of body surface involved

Primary outcomes

1

Description

pain

Timepoint

during change dressing

Method of measurement

oucher

2

Description

Physiologic Indicators

Timepoint

during dressing change

Method of measurement

check list

Secondary outcomes

empty

Intervention groups

1

Description

first Intervention group: Vision Distraction during dressing change with animation play

Category

Treatment - Other

2

Description

Intervention group: Auditory Distractions with music play during dressing change

Category

Treatment - Other

3

Description

Control group: Non intervention

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital, Burnig Ward

Full name of responsible person

Pegah Sharifiyan

Street address

Hamadan Besta Hospital

City

Hamadan

Province

Hamadan

Postal code

6561065810

Phone

+98 81 3252 0683

Email

rsharifian7@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeed Bashiriyan

Street address

Shahid Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

6561065810

Phone

+98 81 3252 0683

Email

s.bashirian@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Arash Khalili

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Pediatric Nursing

Street address

Sfahid Fahmideh Bulvard

City

Hamadan

Province

Hamadan

Postal code

6517625432

Phone

+98 81 3838 0535

Email

arash5920@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Fatemeh Cheraghi

Position

Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahid Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

6561065810

Phone

+98 81 3252 0355

Email

f.cheraghi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Arash Khalili

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahid Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

6561065810

Phone

+98 81 3252 0355

Email

arash5920@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available