

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Effect of virtual reality distraction on anxiety from intravenous catheter placement and adherence to treatment in children 6 to 15 years with cancer

Protocol summary

Study aim

Reduce anxiety during the venous process

Design

The present study is a single blind randomized clinical trial study in which 6 to 15 year old children referred to outpatient chemotherapy ward of Dr. Sheikh Hospital who meet the inclusion criteria and meet the inclusion criteria. And after obtaining consent based on the permutation block they will be divided into two groups.

Settings and conduct

The present study is a single blind clinical trial study in which the study units were selected from 6-15 year old children referred to outpatient chemotherapy ward of Dr. Sheikh Hospital and met the inclusion criteria. Obtaining consent based on the permutation block will fall into two groups.

Participants/Inclusion and exclusion criteria

Informed consent to participate in the research Children aged 6 to 15 years Children with cancer with a history of venous puncture in the maintenance phase The child should be fully alert. The patient is inclined to use virtual glasses. Use of distal organs vessels

Intervention groups

Intervention group of children aged 6-15 years referred to chemotherapy ward Patients with a history of intravenous puncture in the maintenance phase who will receive virtual reality glasses in the intervention group to reduce anxiety during venipuncture. People in the control group are the same as those in the intervention group, which will have a routine procedure of venipuncture.

Main outcome variables

Reduce Anxiety and Stress in Children during the Venous Disease; More Pediatric Co-operation and Adherence in the Disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190815044536N1**

Registration date: **2020-03-06, 1398/12/16**

Registration timing: **prospective**

Last update: **2020-03-06, 1398/12/16**

Update count: **0**

Registration date

2020-03-06, 1398/12/16

Registrant information

Name

Mohammadreza Mosaddegh hesari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3760 6514

Email address

mosaddeghmr1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of virtual reality distraction on anxiety from intravenous catheter placement and adherence to treatment in children 6 to 15 years with cancer

Public title

The effect of virtual reality on catheter insertion anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent to participate in the research ..
Children aged 6 to 15 years Children with cancer with a history of venous puncture in the maintenance phase
The child should be fully alert The patient is inclined to use virtual glasses Use of distal organs vessels

Exclusion criteria:

"Use of proximal child vessels for angiectomy" "Children over 15 years or under 6 years" "Children with cancer before entering the maintenance phase of treatment"

Age

From **6 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Research units from the research community that meet the research criteria will first be selected as accessible and purpose-based, and then randomly assigned to a 4-block permutation method in two virtual reality and control groups.

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 Gonabad University of Medical Sciences

Street address

Shahid Gharani Boulevard, Shahid Gharani 2, Dr. Sheikh Mashhad Pediatric Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9188766956

Approval date

2019-08-05, 1398/05/14

Ethics committee reference number

IR.GMU.REC.1398.086

Health conditions studied

1

Description of health condition studied

Anxiety in children with cancer during the process of obtaining an angiocut

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety score in the observation tool(OSBD-R)

Timepoint

Measuring and observing anxious behavior 5 minutes before and immediately after the intervention

Method of measurement

Anxiety Assessment Tool (OSBD-R) A researcher-made treatment adherence assessment tool

Secondary outcomes

1

Description

heart beat

Timepoint

Before the intervention, during the intervention, immediately after the intervention

Method of measurement

Pulse Oximeter Device

2

Description

Arterial Blood Oxygen Level

Timepoint

Before the intervention, during the intervention, immediately after the intervention

Method of measurement

Pulse Oximeter Device

Intervention groups

1

Description

Evaluation of venous placement and venous placement will be undertaken as the glasses are put on and the child calming clip begins to air. Anxiety levels will be measured and recorded by standard instruments before and immediately after the venous process is completed. To assess treatment adherence at the next follow-up (one month later) in the intervention and control group, the self-adherence questionnaire of treatment adherence will be completed by the researcher by interviewing parents or children.

Category

Behavior

2

Description

Anxiety tool will be completed before and after the vein is completed. To assess treatment adherence at the next follow-up (one month later) in the intervention and control group, the self-administered adherence questionnaire will be completed by the researcher by interviewing parents or children.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Sheikh Mashhad Pediatric Hospital

Full name of responsible person

Mohammad Reza Mosadegh Hesari

Street address

Dr. Sheikh Pediatric Hospital, Shahid Gharani 1, Shahid Gharani Boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

9188766956

Phone

+98 51 3726 9021

Email

MosaddeghMR1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Imam Khomeini street, Gonabad,

City

Mashhad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 3028

Fax

+98 51 8722 3814

Email

info@gmu.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Gonabad University of Medical Sciences

Proportion provided by this source

20

Public or private sector

Private

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

Gonabad University of Medical Sciences

Full name of responsible person

Mohammad Reza Mossadegh Hesari

Position

Head of Chemistry Department of Sheikh Mashhad Pediatric Hospital

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Dr. Sheikh Pediatric Hospital, Martyr Gharani 6. Shahid Gharani Boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

9188766956

Phone

+98 51 3726 9021

Email

MosaddeghMR1@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Reza Mossadegh Hesari

Position

Head of Chemistry Department of Sheikh Mashhad
Pediatric Hospital

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Dr. Sheikh Pediatric Hospital, Shahid Gharani 6,
Shahid Gharani Boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

9188766956

Phone

+98 51 3604 6516

Email

MosaddeghMR1@mums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Reza Mossadegh Hesari

Position

Head of Chemistry Nursing and Pediatric Hospital of
Dr. Sheikh Mashhad

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Dr. Sheikh Pediatric Hospital, Shahid Gharani 6,
Shahid Gharani Boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

9188766956

Phone

+98 51 3604 6516

Email

MosaddeghMR1@mums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All potential data can be shared after unidentifiable
people.

When the data will become available and for how long

Start of access period from 1399

To whom data/document is available

Researchers working in academic and scientific
institutions

Under which criteria data/document could be used

To guide and design the type of study and way of
working for researchers working in academic and
scientific institutions

From where data/document is obtainable

1.Email address:MosaddeghMR1@mums.ac.ir 2.2.
Contact with phone number:09151179193

What processes are involved for a request to access data/document

Request an Email Address and Submit a Request for
Voice and No Replies Contact Cell Phone: 09151179193

Comments