Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

Comparison of the effectiveness of two methods of distraction with Animation cartoon and distraction cards on pain Perception after Blood sampling and parental satisfaction in children 3-6 years

Protocol summary

Study aim

Comparison of the effectiveness of two methods of distraction with Animation cartoon and distraction cards on pain Perception after Blood sampling and parental satisfaction in children 3-6 years

Design

This clinical trial involving 90 children that randomly allocated in three groups of 30 people in Animation cartoon intervention group,30 people in distraction cards intervention group and 30 people in control group .

Settings and conduct

Children's departments of Akbar Children's Pediatric Hospital

Participants/Inclusion and exclusion criteria

Entry Criterion: •Children 3-6 years •The child has no mental or psychological problem according to the doctor's diagnosis. •The absence of acute and severe pain or the need for urgent emergency procedures, according to the diagnosis of the doctor in charge of treatment. •Presence of a physician's written instruction for blood sampling 5.Parental presence No entry Criterion: •Have neuro-developmentally delayed •Have vision and hearing impairment and verbal difficulties •He used analgesic Such as phenobarbital and diazepam 6 hours before blood sampling

Intervention groups

In animation cartoon intervention group, animation cartoon display is used 5 minutes before blood sampling until the end of blood sampling. In intervention group of distraction cards, distraction cards is used From start to end of blood sampling . Blood sampling in the control group without intervention.

Main outcome variables

Pain Perception after Blood sampling and parental satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171110037347N1**
Registration date: **2019-01-03, 1397/10/13**
Registration timing: **retrospective**

Last update: **2019-01-03, 1397/10/13**
Update count: **0**

Registration date

2019-01-03, 1397/10/13

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38413007

Email address

ebrahimzadehz941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2018-07-01, 1397/04/10

Actual recruitment start date

2018-04-03, 1397/01/14

Actual recruitment end date

2018-07-01, 1397/04/10

Trial completion date

2018-07-01, 1397/04/10

Scientific title
Comparison of the effectiveness of two methods of distraction with Animation cartoon and distraction cards on pain Perception after Blood sampling and parental satisfaction in children 3-6 years

Public title
Effect of Cartoon Animation and Distraction Card on Reducing the Pain of Children 3-6 Years Blood sampling and Parental Satisfaction

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
children 3-6 years The child has no mental or psychological problem according to the doctor's diagnosis. The absence of acute and severe pain or the need for urgent emergency procedures, according to the diagnosis of the doctor in charge of treatment. Presence of a physician's written instruction for blood sampling Parental presence

Exclusion criteria:
Have neuro-developmentally delayed Have vision and hearing impairment and verbal difficulties He used analgesic Such as phenobarbital and diazepam 6 hours before blood sampling

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: **90**
Actual sample size reached: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Lottery using blocking The lottery by blocking is that we have three groups A = animation cartoon group B = Band of Deviation cards C = control group So we have 6 modes for sample selection: ABC-ACB-BAC-BCA -CAB -CBA By dropping these dice, it will be determined how the sampling procedure is organized, for example by removing the ACB dice first by intervening in the animation cartoon group, then in the control group, and then in the distraction card group.

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
The Ethics Committee of Mashhad University of Medical Sciences

Street address
Mashhad Nursing -Midwifery College,Ibn Sina street, Doctor's Crossroads, University Street

City
Mashhad

Province
Razavi Khorasan

Postal code
13944-91388

Approval date
2018-02-12, 1396/11/23

Ethics committee reference number
IR.MUMS.REC.1396.368

Health conditions studied

1

Description of health condition studied
Distraction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain perception after blood sampling

Timepoint
After Blood sampling and two minutes after Blood sampling

Method of measurement
Wong and Baker pain tool

2

Description
Parental satisfaction

Timepoint
After blood sampling

Method of measurement
Parental satisfaction questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The executive protocol in the animation cartoon First

intervention group is such that after the child He was guided to blood sampling room .The second nurse communicates with the child and then Displayed an animated cartoon Using the tablet 5 minutes before blood sampling It continues until the end of the blood sampling. Blood sampling will be done by the first nurse.

Category

N/A

2

Description

The executive protocol in the distraction cards Second intervention group is such that after the child guided to blood sampling room .The second nurse communicates with the child and showed the cards to the child(the distraction cards is that distraction cards are cards of dimensions 5 by 8 cm, with various shapes and images, and questions based on the age of the child behind the screen) and told the child that "You can answer my questions if you pay attention to the cards carefully." When the child begins to look carefully at the card, the first nurse starts to take blood and the second nurse begins to ask questions during until end blood sampling, such as "How many babies are you in the picture?" Or " All the boars have a few points? " , "Can you see the filo in your picture?", "How many monkeys do you see in the picture?" etc.

Category

N/A

3

Description

Control group: Blood sampling in the control group will be performed routinely without intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Akbar mashhad children's hospital

Full name of responsible person
Ebrahimzadeh zeinab

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Mashhad Nursing -Midwifery College,Ibn Sina street, Doctor's Crossroads, University Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Deputy Research and Technology

Street address
Mashhad Nursing -Midwifery College,Ibn Sina street, Doctor's Crossroads, University Street

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Ebrahimzadeh zeinab

Position
Master of child nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Information on the main outcome
When the data will become available and for how long
Start the access period one year after the print results
To whom data/document is available
Researchers working in academia and academia
Under which criteria data/document could be used
By request by valid email
From where data/document is obtainable
Email
What processes are involved for a request to access data/document
By request, by email and the destination will be available to people
Comments