Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Multisensory Stimulation care plan on pain of Infants during Eye Examination for Retinopathy

Protocol summary

Study aim
Determining the effect of multi-sensory stimulation care program on pain relief from eye examination of infants with retinopathy

Design
A concealed, randomized,single-blinded, clinical trial with a parallel-group design of 50 patients

Settings and conduct
The purpose of this study is to compare the effect of a multi-sensory stimulation care program on the amount of eye examination pain in infants with Retinopathy. This is a concealed, randomized,single-blinded, clinical trial design of 50 patients with retinopathy who will be referred to the clinic of Tabriz Nikokari hospital. First, by drawing the letters A and B, they are assigned to the intervention and control groups, respectively. Then divided into two groups of twenty-five using Rand List software. The infant has not used any sedative medication for the past 24 hours. In group A In infants, foot massage, sucking stimulation and noise distraction will receive. but group B does not receive any intervention.pain score will be measured 5 minutes before and after the examination and during the examination. The data analyzer will be blinded to the groups.

Participants/Inclusion and exclusion criteria
Infants with retinopathy examined between the ages of 2 to 6 months and with no oral ulcer and anomalies in the leg area

Intervention groups
Both groups of children will receive a 0.5% tetracaine drop an hour before the examination 3-time interval of 5 minutes each. In infants who will be included in the intervention group during the insertion of the speculum ,pacifier to stimulate the sucking sensation, the sound of a rattle to stimulate hearing and foot massage will be used. But in the control group, none of these interventions were performed and only the infants' pain score would be measured.

Main outcome variables
Children under study will benefit from a non-pharmacological pain-relieving method.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130617013691N11**
Registration date: **2020-01-21, 1398/11/01**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-21, 1398/11/01**
Update count: **0**

Registration date
2020-01-21, 1398/11/01

Registrant information

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Mohammad Arshadi Bostanabad
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-21, 1398/08/30

Expected recruitment end date
2020-07-21, 1399/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Multisensory Stimulation care plan on pain of Infants during Eye Examination for Retinopathy

Public title
Effect of Multisensory Stimulation care plan on pain of Retinopathy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Infants with retinopathy 2-6 months old The infant is calm and awake Do not take painkillers or sadatives for the past 24 hours Mother of the baby to be present Parents of infants consent to participate in the study
Exclusion criteria:
Do not attempt to insert the spaculum more than once There is no need for urgent resuscitation during the examination History of CPR, operation, Intraventricular hemorrage more than grade 2, Major infant birth defect such az cadiac and CNS disaeses Oral problems such as cleft palate and oral ulsers No abnormality in the leg area
Age
From **2 months** old to **6 months** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Using a checklist prepared using Randlist software, the first group will be assigned to the control group by drawing one of the letters a or b and the other letter by the intervention group. A and B are divided and placed in opaque envelopes by the research assistant (allocation concealment). Parents are asked to select one of the envelopes.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
seyed o Shohada Hospital, 17 Shahrivar Blvd, urmia city
City
Tabriz
Province
East Azarbaijan
Postal code
5718748983
Approval date
2019-10-27, 1398/08/05
Ethics committee reference number
IR.TBZMED.REC.1398.757

Health conditions studied

1

Description of health condition studied
Retinopathy
ICD-10 code
H36
ICD-10 code description
Retinal disorders in diseases classified elsewhere

2

Description of health condition studied
Pain
ICD-10 code
R52
ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
Pain score in Neonatal Infant Pain Scale
Timepoint
Five minutes before an eye examination/During the eye examination/Five minutes after doing eye examination
Method of measurement
Neonatal Infant Pain Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:One hour before eye examination, 0.5% tetracaine drops will be given 3 times each time for 5 minutes.Then, 5 minutes before the examination, during the insertion of the speculum, and 5 minutes after the speculum is removed, the pain score and the physiological data of the infant will be recorded.After recording basic data,The researcher's help will try to keep one standard, small, short, full-length, one- six month-old baby pacifier in the infants mouth.(The same type pacifier will be used for all infants).This will continue during the examination.After removing the speculum from the eye which means that the examination is completed,The pacifier will come out of the baby's mouth.Simultaneously, foot massage will be performed slowly by the researcher 2 minutes before the eye examination.After removal of the spaculum, the foot massage will be discontinued immediately.One minute before inserting the spaculum, distracting through the sound of a toy,Shaken by the mother done.At the end of the examination, the rattle will also be muted.

Category

N/A

2

Description

Control group: One hour before eye examination, 0.5% tetracaine drops will be given 3 times each time for 5 minutes.Then, 5 minutes before the examination, during the insertion of the speculum, and 5 minutes after the speculum is removed, the pain score and the physiological data of the infant will be recorded.There is no intervention during the examination.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Nikukari Training Center Clinic

Full name of responsible person

Mohamad Arshadi

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Seyedoshohada Hospital, 17 Shahrivar Blvd, Urmia city

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Sponsors / Funding sources

1

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mohamad Arshadi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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
Yes - There is 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
Only part of the data, such as information about the main outcome, can be shared.
When the data will become available and for how long
Start of access period 6 months after printing results
To whom data/document is available
Researchers at academic and research institutes can apply for data if needed.
Under which criteria data/document could be used
Use of this research data in similar research is permitted unless noted and copied.
From where data/document is obtainable
Applicants can apply for documentation or data through the following Send message to email: saba.moghtader73@gmail.com Send message to email: Arshadi_m@yahoo.com Call the phone number: 09141392603
What processes are involved for a request to access data/document
Seven days after receipt of the request the applicant will be provided with the documentation or data file.
Comments