

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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

Name

Mohammad Arshadi Bostanabad

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3479 6770

Email address

arshadi@tbzmed.ac.ir

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 sedatives 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 speculum more than once There is no need for urgent resuscitation during the examination History of CPR, operation, Intraventricular hemorrhage more than grade 2, Major infant birth defect such as cardiac and CNS diseases Oral problems such as cleft palate and oral ulcers 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 speculum, the foot massage will be discontinued immediately. One minute before inserting the speculum, 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

Street address

Seyedoshohada Hospital, 17 Shahrivar Blvd, Urmia city

City

Tabriz

Province

East Azarbaijan

Postal code

5718748983

Phone

+98 44 3346 2362

Email

saba.moghtader73@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohamad Arshadi

Street address

Seyedoshohada Hospital, 17 Shahrivar Blvd, Urmia City

City

Tabriz

Province

East Azarbaijan

Postal code

5718748983

Phone

+98 44 3346 2362

Email

saba.moghtader73@gmail .com

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

Street address

Seyedoshohada Hospital, 17 Shahrivar Blvd, Urmia City

City

Tabriz

Province

East Azarbaijan

Postal code

5718748983

Phone

+98 44 3346 2362

Email

saba.moghtader73@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohamad Arshadi Bostanabad

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing, South Shariati St., Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5718748983

Phone

+98 41 3479 6770

Email

Arshadi_m@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohamad Arshadi Bostanabad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing, South Shariati St., Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5718748983

Phone

+98 44 3479 6770

Email

Arshadi_m@yahoo.com

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