

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Investigating the effect of peppermint nanoemulsion gel on children's pain, fear and anxiety during venipuncture

Protocol summary

Study aim

Determining the effect of peppermint nanoemulsion gel on children's pain, fear and anxiety during venipuncture

Design

A clinical trial with a control group, with parallel, three-way-blind, randomized groups on 100 patients, was used for randomization software.

Settings and conduct

This study is conducted in Imam Reza Bojnord Hospital. Children referred to the hospital who meet the other conditions for entering the study will be included in the study and will be divided into two intervention and control groups. External use of peppermint nanoemulsion will be used for the intervention group and placebo will be used for the control group. In this study, blinding is done with the help of a placebo for the participants, the researchers present at the bedside and the statistical analyzer.

Participants/Inclusion and exclusion criteria

Consent of the child and the consent of the child's companion (legal guardian) Absence of cognitive problems Not receiving painkillers and sedatives in the last 24 hours Age from 7 years to the end of 12 years Absence of disease or life-threatening condition Absence of disease with chronic pain No vision problems Absence of fever of 38 degrees and above

Intervention groups

The control group will include the use of placebo (nanoemulsion without peppermint essence) at the venipuncture site and the intervention group will be divided into the use of nanoemulsion containing peppermint essence at the venipuncture site.

Main outcome variables

pain fear anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201027049165N3**

Registration date: **2024-02-07, 1402/11/18**

Registration timing: **prospective**

Last update: **2024-02-07, 1402/11/18**

Update count: **0**

Registration date

2024-02-07, 1402/11/18

Registrant information

Name

Hassan Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

abbasih982@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-09-20, 1403/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of peppermint nanoemulsion gel on children's pain, fear and anxiety during venipuncture

Public title

Investigating the effect of peppermint nanoemulsion gel on children's pain, fear and anxiety during venipuncture

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The consent of the child and the consent of the child Age from 7 years to the end of 12 years

Exclusion criteria:

The presence of cognitive problems Receiving painkillers and sedatives in the last 24 hours Disease or life-threatening condition Having a disease with chronic pain Vision problems Having a fever of 38 degrees or higher

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Children will be randomly divided into 1-control and 2-intervention groups using the sequence generated by the Randomization site and using sealed envelopes to hide the allocation.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In order to blind the evaluators of nanoemulsions, they will be marked in similar and unnamed cases with special signs, each of which represents a nanoemulsion.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

North khorasan university of medical science

Street address

Dolat Ave

City

Bojnuord

Province

North Khorasan

Postal code

74877-94149

Approval date

2024-01-17, 1402/10/27

Ethics committee reference number

IR.NKUMS.REC.1402.168

Health conditions studied

1

Description of health condition studied

Establish venous access

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

After the procedure

Method of measurement

Wong baker-facial expression rating scale

2

Description

fear

Timepoint

After the procedure

Method of measurement

Child fear inventory (CFI)

3

Description

anxiety

Timepoint

After the procedure

Method of measurement

Spielberger anxiety questionnaire and blood cortisol level measurement

Secondary outcomes

1

Description

pulse rate

Timepoint

Before and after the procedure

Method of measurement

Nevometrics pulse oximeter device

2

Description

Oxygen saturation

Timepoint

Before and after the procedure

Method of measurement

Nevometrics pulse oximeter device

3

Description

Blood Pressure

Timepoint

Before and after the procedure

Method of measurement

ALPK2 dial sphygmomanometer cuff

Intervention groups

1

Description

Intervention group: Nanoemulsion containing peppermint essential oil will be used 15 minutes before vein extraction (21) through external use in the size of 5 x 5 cm on the skin surface of the desired area for vein extraction.

Category

Prevention

2

Description

Control group: The placebo will be used 15 minutes before vein extraction (21) through external use, measuring 5 x 5 cm on the skin surface of the desired area for vein extraction.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Bojnourd Hospital

Full name of responsible person

Hasan Abasi

Street address

Bojnourd- Shahyar St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Hasan Abasi

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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

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Hassan Abbasi

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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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 information and data including the study protocol, statistical analysis map and results will eventually be published in full in the dissertation.

When the data will become available and for how long

After final approval and publication of the dissertation

To whom data/document is available

There are no restrictions

Under which criteria data/document could be used

Can be used within the framework of university regulations

From where data/document is obtainable

Hassan Abbasi, 09115678048,
www.abbasih1612@gmail.com

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

Applicants for research data can contact the main authors of the study to announce their request and after obtaining the necessary agreements, the information will be provided to them.

Comments