

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of regular breathing on severity of pain, fear and physiological indices of venipuncture in the elderly

Protocol summary

Study aim

Determining The effect of rhythmic breathing on the severity of pain, fear and physiological indices of venipuncture in the elderly

Design

Clinical trial with control group, with parallel groups, without blindness, randomized simple random sampling, 100 samples

Settings and conduct

The experimental group consisted of 50 patients and 50 subjects in the control group. First, blood pressure and heart rate were measured in both groups. The test group performed rhythmic breathing for two minutes and no intervention in the control group. After venipuncture in two groups, patients fear and pain measure by "visual analog scale". Blood pressure and heart rate are also measure in two groups.

Participants/Inclusion and exclusion criteria

Participants included elderly people referred to Shahid Sadoughi Hospital in Yazd for cataract surgery. Inclusion criteria: willingness to participate in research, Age 60-75 No entry criteria: Inability to perform rhythmic breathing, Addiction to opiates or strong analgesic, receive pain medication before surgery, Severe hearing visual mental and cognitive problems, sensory disturbances in the upper limb and neuropathic disorders and peripheral vascular diseases, Disease or inflammation or redness at the site of stroke

Intervention groups

Intervention involves regular breathing, which has been pre-trained and performed for two minutes. The procedure for regular breathing is such that the patient lays in a comfortable position, closes his eyes and performs a long, deep nose through the nose with 3 numbers. Then he will hold his breath in the lungs and count up to 3, then with the 3 numbers of a slow exhalation through the mouth. That along with the inspiratory or expiratory silent count one thousand one, one thousand two, etc. The control group does not do

anything.

Main outcome variables

severity of pain, fear and physiological indices of venipuncture

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190115042369N1**

Registration date: **2019-02-13, 1397/11/24**

Registration timing: **retrospective**

Last update: **2019-02-13, 1397/11/24**

Update count: **0**

Registration date

2019-02-13, 1397/11/24

Registrant information

Name

Maryam Dehghany tafti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 1751

Email address

dehghany.ma@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-13, 1397/05/22

Expected recruitment end date

2018-09-13, 1397/06/22

Actual recruitment start date

2018-08-13, 1397/05/22

Actual recruitment end date

2018-09-10, 1397/06/19

Trial completion date

2018-09-13, 1397/06/22

Scientific title

The effect of regular breathing on severity of pain, fear and physiological indices of venipuncture in the elderly

Public title

The effect of regular breathing on severity of pain, fear and physiological indices of venipuncture in the elderly

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

willingness to participate in research Age 60-75 years

Exclusion criteria:

Inability to perform rhythmic breathing Addiction to opiates or strong analgesic receive pain medication before surgery Severe hearing, visual, mental and cognitive problems There are sensory disturbances in the upper limb and neuropathic disorders and peripheral vascular diseases Disease or inflammation or redness at the site of stroke

AgeFrom **60 years** old to **75 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **100**Actual sample size reached: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

A simple random method using Random Allocation software

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 in Shahid Sadoughi University of Medical Sciences Yazd

Street address

Central building of Shahid Sadoughi University, Shahid Bamonar Square, Yazd

City

yazd

Province

Yazd

Postal code

8916978477

Approval date

2018-06-26, 1397/04/05

Ethics committee reference number

ir.ssu.rec.1397.049

Health conditions studied**1****Description of health condition studied**

Cataract Surgery

ICD-10 code

H25

ICD-10 code description

Age-related cataract

Primary outcomes**1****Description**

Intensity of pain

Timepoint

After venipuncture in the experimental and control groups

Method of measurement

Visual analog scale

2**Description**

Fear of venipuncture

Timepoint

After venipuncture in the experimental and control groups

Method of measurement

Visual analog scale

3**Description**

Heart rate

Timepoint

Before and after the venipuncture in the test and control groups

Method of measurement

Digital manometer

4**Description**

blood pressure

Timepoint

Before and after the venipuncture in the test and control groups

Method of measurement
Digital manometer

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: In regular breathing group after regular breathing training and fixing, regular breathing is done for two minutes. The procedure for regular breathing is that the patient is required to lie in a comfortable position, close his eyes, and with 3 numbers one deep and long tail through the nose, then hold his breath in the lungs, and until 3 Then, with the 3rd issue of the first one, slowly exhale through the mouth. In this way, with a tail or an exhale, one thousandth one, one thousand, two and so on.

Category

Behavior

2

Description

Control group: There is no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Maryam Dehghany Tafti

Street address

Shahid Sadoughi Hospital, Ebne Sina Evenue, Shahid Ghandi Blvd, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Behnaz Anjzab

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Maryam Dehghany Tafti

Position

Master student of Geriatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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