Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Age
From **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 Bahonar 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

Street address

NO.8917774894, Faculty of Nursing and Midwifery, Bou Ali Ave, Timsar Fallahi Blvd, Safayeh, Yazd Town

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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
Name of organization / entity
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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