Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of auriculotherapy education on anxiety, sleeps quality, pain and hemodynamic parameters of patients after Coronary artery bypass graft surgery (CABG)

Protocol summary

Study aim
Determining the effect of ear acupressure training on anxiety, sleep quality, pain and hemodynamic indicators of patients after coronary artery bypass surgery

Design
A clinical trial with a control group with parallel groups. one blind strain. randomized. phase 3 on 164 patients. randomization using the output of Random allocation2 software.

Settings and conduct
After reviewing the waiting list of patients undergoing heart surgery at Fatemeh Zahra Hospital (S) of Mazandaran University of Medical Sciences, 164 patients will be selected non-randomly and available and using the software to Randomly, they are placed in two intervention and control groups. Then the intervention is performed four times a day by the researcher from one day before the surgery and up to three days after the surgery, but in the placebo group skin patches without vaccaria seeds are attached in unrelated places. Completing the questionnaires before the intervention and after the end of the intervention will be done by the participants.

Participants/Inclusion and exclusion criteria
Inclusion: Age 18 years and above. Not having any history of taking psychiatric drugs. Patients under general anesthesia. Using only ibuprofen pain reliever. Creatinine in the range of 1.2 - 0.7 mg/DL Exclusion: Patients with any history of eczema, dermatitis, etc. Complications of surgery include bleeding

Intervention groups
Intervention group: Sticking special adhesives containing vaccaria seeds on the points of the ear that affect anxiety, pain intensity, sleep quality and hemodynamic indicators of patients and their pressure from one day before surgery and up to three days after surgery, four Times per day by the researcher. Control group: pasting skin patches without vaccaria seeds on irrelevant points of the ear and slight pressure on them

Main outcome variables
Anxiety, Pain intensity, Sleep quality, Hemodynamic indicators

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230116057134N1**
Registration date: **2023-04-10, 1402/01/21**
Registration timing: **prospective**

Last update: **2023-04-10, 1402/01/21**
Update count: **0**

Registration date
2023-04-10, 1402/01/21

Registrant information

Name
Mohammad hossein Hakimi

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-21, 1402/02/31

Expected recruitment end date
2023-07-22, 1402/04/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of auriculotherapy education on anxiety, sleeps quality, pain and hemodynamic parameters of patients after Coronary artery bypass graft surgery (CABG)

Public title
The effect of auriculotherapy education on anxiety, sleeps quality, pain and hemodynamic parameters of patients after Coronary artery bypass graft surgery (CABG)
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 years and above Not having any history of taking psychiatric drugs (delirium, insomnia, etc.), based on the medical history and by reviewing the patient's hospitalization file and looking at the patient's medications Patients under general anesthesia (by reading the patient procedure description sheet, after surgery, which is available in the patient file) Using only ibuprofen pain reliever based on the department's routine in the form of 400 mg every 8 hours (they should not use Gellophane 4 hours before the intervention) Creatinine in the range of 1.2 - 0.7 mg/DL
Exclusion criteria:
Patients with any history of eczema, dermatitis, etc. Complications of surgery include bleeding
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **164**
Randomization (investigator's opinion)
Randomized
Randomization description
Research participants will be randomly divided into two intervention groups and control groups. The randomization unit will be the participants. For blinding, one letter is assigned to each group (A: ear acupressure intervention group and B: comparison group). Then with the help of the online method on the site https://www.sealedenvelope.com/simple-randomiser/v1/lists or using the random allocation2 software and without individual intervention, the allocation sequence will be created. Then, to hide the allocation sequence, the sequence is written on the sheets and placed in sealed envelopes in order.
Blinding (investigator's opinion)
Single blinded
Blinding description
A placebo group will be used for blinding. The placebo group will be visited like the intervention group. The researcher will stick the skin patches without Vaccaria seeds on the skin of the ear, will be present at the patient's bedside and will talk to the patient. In the placebo group, irrelevant points of the ear are pressured, even though it is insignificant, none of the two groups know which group they will be in.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
The headquarters of Mazandaran University of Medical Sciences, Imam Square (RA), the beginning of Valiasr Highway (AJ)
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Sari
Province
Mazandaran
Postal code
4815733971
Approval date
2022-10-16, 1401/07/24
Ethics committee reference number
IR.MAZUMS.REC.1401.339

Health conditions studied

1

Description of health condition studied
Investigating the effect of ear acupressure training on anxiety of patients after coronary artery bypass surgery
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

2

Description of health condition studied
Investigating the effect of ear acupressure training on sleep quality of patients after coronary artery bypass surgery

ICD-10 code
G47.01
ICD-10 code description
Insomnia due to medical condition

Primary outcomes

1

Description
Assessment of patients' anxiety after coronary artery bypass surgery
Timepoint
Evaluation of patients' anxiety in two intervention and control groups immediately after the intervention and four days after the intervention
Method of measurement
The use of Spiel Berger questionnaire

2

Description
Evaluation of sleep quality of patients after coronary artery bypass surgery
Timepoint
Evaluation of sleep quality of patients in two intervention and control groups immediately after the intervention and four days after the intervention
Method of measurement
The use of Saint Mary's questionnaire

Secondary outcomes

1

Description
Assessment of pain intensity in patients after coronary artery bypass surgery
Timepoint
Evaluation of pain intensity of patients in two intervention and control groups immediately after the intervention and four days after the intervention
Method of measurement
The use of Visual Analogue pain Scale

2

Description
Evaluation of hemodynamic indicators of patients after coronary artery bypass surgery
Timepoint
Evaluation of hemodynamic indicators of patients in two intervention and control groups immediately after the intervention and four days after the intervention
Method of measurement
Use of monitoring device

Intervention groups

1

Description
Intervention group: Auricular acupressure intervention using special adhesives containing vaccaria seeds on points of the ear (Shen Men, zero point, pelvis, abdomen, endocrine, uterus) which is effective on anxiety, pain intensity, sleep quality and hemodynamic indicators of patients. is glued The intervention will be carried out by the researcher from one day before the surgery and up to three days after the surgery four times during the day (three times in the morning and once in the evening) and each of the points will be compared for one minute with The finger is pressed. The material used in this study is special auriculotherapy adhesives containing vaccaria seeds, which is a product of China. This product will be available from medical equipment stores.
Category
Treatment - Other

2

Description
Control group: They will be visited similarly to the intervention group. The researcher pastes skin patches without Vaccaria seeds on the skin of the ear. And he will only be present at the patient's bedside and talk to the patient. In the placebo group, irrelevant points of the ear are pressured, although slightly
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemeh Zahra Hospital (S)
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Deputy Research and Technology- Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
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Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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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