Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of self-hypnosis on acute pain and delirium in adult patients after coronary artery bypass surgery

Protocol summary

Study aim
Determining the effect of self-hypnosis on acute pain and delirium in adult patients after coronary bypass surgery

Design
A clinical trial with a control group, without blinding, randomized on 84 patients, the block method was used for randomization.

Settings and conduct
The study is on patients of Shahid Rajaei Heart Institute in Tehran without blinding. The intervention group is self-hypnotized 3 times before surgery. Acute pain and delirium are measured after surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age group 18-70;Ability to speak and understand Farsi language Hypnotizability score > 25 based on the Stanford Form C scale Elective coronary artery bypass surgery;written consent to participate in the research and telephone follow-up by the researcher Patient access to smartphone and hands-free; no hearing impairment RASS = 0 ;GCS = 14;Do not have History of psychiatric disorders: psychosis, severe depression, claustrophobia, acrophobia, obsessive personality, paranoid personality; Do not have a history of seizures and epilepsy - Exclusion criteria: Surgery is canceled or postponed ، Emergency surgery Death during surgery ، Refusal to continue studying ; The patient should listen to the hypnosis file less than 3 times ; Receiving continuous intravenous infusion of Dex-medtomidine combined with morphine

Intervention groups
patients of the control group, there is no intervention ; intervention for the case group 48 hours before the surgery: explaining how to do the work, removing any misconceptions about hypnosis, teaching self-hypnosis through the I HYPNOSIS software (author of the work, Dr. Inayat Elah Shahidi) 24 hours before surgery: self-hypnosis by the patient On the morning of surgery (before surgery): self-hypnosis by the patient

Main outcome variables
pain; delirium

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240718062455N1**
Registration date: **2024-07-30, 1403/05/09**
Registration timing: **prospective**

Last update: **2024-07-30, 1403/05/09**
Update count: **0**

Registration date
2024-07-30, 1403/05/09

Registrant information

Name
Sajede Sajadi

Name of organization / entity
Shaheed rajaie cardiovascular medical and research institute

Country
Iran (Islamic Republic of)

Phone
+98 21 2229 1498

Email address
sajedesjd2010@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-31, 1403/05/10

Expected recruitment end date
2024-09-21, 1403/06/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-hypnosis on acute pain and delirium in adult patients after coronary artery bypass surgery

Public title

Effect of self-hypnosis on acute pain and delirium

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Ability to speak and understand Farsi language Hypnotizability score of 25 and above based on the Stanford Form C scale Elective coronary artery bypass surgery Written consent to participate in the research and telephone follow-up by the researcher Have no hearing impairment RASS = 0 GCS =15 Do not have History of psychiatric disorders: psychosis, severe depression, claustrophobia, acrophobia, obsessive personality, paranoid personality Do not have a history of seizures and epilepsy Patient access to smartphone and hands-free

Exclusion criteria:

Emergency surgery Refusal to continue studying

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, balanced block, Randomization unit: individual 4 permutations of letters AB become six blocks of four. Opaque envelope sealed with random sequence is used for concealment Random sequence: Each sequence is placed inside the envelope. The envelopes are placed in the box and opened according to the order in which the participants entered one of the envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Rajaie Cardiovascular, Medical and Research Institute

Street address

No 39, lavasani Ave, Farmanieh

City

Tehran

Province

Tehran

Postal code

1954645386

Approval date

2024-06-15, 1403/03/26

Ethics committee reference number

IR.RHC.REC.1403.034

Health conditions studied

1

Description of health condition studied

Acute pain and delirium after coronary artery bypass surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score based on visual analogue scale

Timepoint

Evaluation of pain 12, 24, 36 and 48 hours after extubation post surgery

Method of measurement

Visual analogue scale

2

Description

Assessment of delirium with Confusion Assessment Method for the Intensive Care Unit

Timepoint

12, 24, 36, 48 hours after surgery

Method of measurement

Confusion Assessment Method for the Intensive Care Unit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Self-hypnosis, using Dr. Inayat Elah Shahidi's self-hypnosis application, 3 times before surgery, 48 and 24 hours and in the morning before surgery, for 20 minutes.

Category

Prevention

2

Description

Control group: there is no intervention by the researcher before surgery, and the patients receive routine care before surgery in the ward.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed rajaie Cardiovascular, Medical & Research institute

Full name of responsible person

Sajede sajadi

Street address

Niayesh corner of Shahid Rajaei Cardiovascular Educational, Research and Therapeutic Institute, next to Mellat Park, Wali Asr St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shaheed Rajaie Cardiovascular, Medical & Research Center

Full name of responsible person

Sajede sajadi

Street address

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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

Shaheed Rajaie Cardiovascular, Medical & Research Center

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

Shaheed rajaie cardiovascular, medical & research institute

Full name of responsible person

Sajede sajadi

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shaheed rajaie cardiovascular, medical & research institute

Full name of responsible person

Sajede sajadi

Position

Master's student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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
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

Title and more details about the data/document
All data can be shared after other identifiable individuals

When the data will become available and for how long
The access period starts 7 months after the results are published

To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
There is no restriction on the type of data analysis The use of documentation is unimpeded by maintaining ethical principles

From where data/document is obtainable
To receive data, send a message to Sajde Sajadi's email sajedesjd2010@gmail.com

What processes are involved for a request to access data/document
After sending the email, the data will be sent at most one week later

Comments