

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Investigating the impact of the presence companion nurse program on the anxiety and physiological indicators of angiography candidate patients in the waiting room

Protocol summary

Study aim

This study investigated the effect of the accompanying nurse's presence program on angiography candidates' anxiety and physiological indicators in the waiting room.

Design

Two-group randomized clinical trial, randomized, on 70 patients, random allocation using Random allocation software

Settings and conduct

The environment of this research was the heart department and angiography waiting room of Razi Medical Education Center in Birjand affiliated to Birjand University of Medical Sciences and Health-Therapeutic Services. In two stages, at the time of entering the waiting room and at the time of entering the angiography room, the accompanying nurse presence program was carried out for each patient individually in the intervention group.

Participants/Inclusion and exclusion criteria

Candidate patients for angiography Inclusion criteria: age 25 to 85 years, angiography is not an emergency patient Exclusion criteria: Life-threatening problems including rhythm disorders (arrhythmias), Waiting time of less than 20 minutes

Intervention groups

Intervention group: accompanying nurse attendance program Control group: cath lab routine program

Main outcome variables

Reducing anxiety, reducing physiological index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230802059007N1**

Registration date: **2024-01-03, 1402/10/13**

Registration timing: **retrospective**

Last update: **2024-01-03, 1402/10/13**

Update count: **0**

Registration date

2024-01-03, 1402/10/13

Registrant information

Name

sajjad salehian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the impact of the presence companion nurse program on the anxiety and physiological indicators of angiography candidate patients in the waiting room

Public title

The effect of the presence companion nurse program on anxiety and physiological indicators of angiography candidate patients	
Purpose	Prevention
Inclusion/Exclusion criteria	
Inclusion criteria:	Angiography is not an emergency patient Hospitalization in the relevant cardiac departments Ability to communicate verbally Being a candidate for an angiography procedure for the first time Not having vision and hearing problems No drug addiction Avoid using sedatives No epilepsy or mental illness No high blood pressure Not receiving anti-anxiety drugs before the procedure Willingness to participate in the study and complete the written informed consent form The patient is not part of the treatment team
Exclusion criteria:	Life-threatening problems including rhythm disorders (arrhythmias) Waiting time of less than 20 minutes Angiography for several times
Age	From 25 years old to 85 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 70
Randomization (investigator's opinion)	Randomized
Randomization description	In this research, According to previous studies, The samples were first selected by the available sampling method and then randomly allocated using Random Allocation software in two intervention (A) and control (B) groups. Therefore, for this purpose, first, the researcher introduced himself to the patients who met the criteria for entering the study, and explanations were given regarding the study and its objectives. Then, following all the ethical and scientific criteria, a list of candidate patients for angiography was prepared and numbered. The target sample was selected by random allocation. Explaining that the allocation of research units to two groups was done using random allocation software is necessary.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Other
Other design features	This study has two groups (intervention and control). The cath lab routine program is carried out in the control group, but the presence companion nurse program is carried out in the intervention group. Only one type of intervention (the presence companion nurse program) is performed on patients in the intervention group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences , Ghafari Street, Birjand, South Khorasan, Iran.

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birjand

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Postal code

۹۷۱۷۸۵۳-۷۶

Approval date

2023-05-10, 1402/02/20

Ethics committee reference number

IR.BUMS.REC.1402.074

Health conditions studied

1

Description of health condition studied

Cardiovascular disease

ICD-10 code

I51.6

ICD-10 code description

Cardiovascular disease, unspecified

Primary outcomes

1

Description

anxiety

Timepoint

Measuring anxiety at the beginning of the study (before the start of the intervention) and after half an hour after the intervention

Method of measurement

Hamilton anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the presence companion nurse program -On the day of angiography, upon entering the waiting room, the patient's anxiety level and

physiological indicators were determined, then the nurse's presence plan was implemented for the patient, after the intervention, when entering the angiography room, the patient's anxiety level and physiological indicators were rechecked. The presence companion nurse program was carried out for each patient individually in the intervention group. In this study, the companion nurse is the researcher. Also, the cath lab routine program was implemented in the control group. Just before entering the waiting room and also the angiography room, the Hamilton anxiety questionnaire was taken. Intervention: Introduction of cath lab space - introduction of personnel and a friendly and trusting atmosphere for the patient - explaining how to perform the angiography procedure in simple language - psychological support (being responsive to the patient's questions) - assuring the patient that we will wait for her until the end of the procedure

Category

Prevention

2

Description

Control group: cath lab routine program - also in the control group, the cath lab routine program was implemented. Before entering the waiting room and also the angiography room, the Hamilton anxiety questionnaire was taken. The routine program of the department is as follows: after patients are delivered by the ward nurse, the patient's information is checked, and the patients are checked for lack of equipment and dentures. Then, the patients wait for the angiography room to be empty.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Birjand Hospital

Full name of responsible person

Sajjad Salehian

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Sponsors / Funding sources

1

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Sajjad Salehian

Position

Master in nursing Student

Latest degree

Bachelor

Other areas of specialty/work

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Position

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data, such as information related to anxiety,
can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are
published

To whom data/document is available

Researchers working in academic institutions of medical
sciences

Under which criteria data/document could be used

Research on angiography candidate patients

From where data/document is obtainable

sajjad salehian - st.sajad73@gmail.com

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

After receiving the email, it will receive the data for one
month.

Comments