Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of multimodal program on anxiety and hemodynamic status in Patients undergoing electrophysiologic interventions in Afshar hospital in Yazd, 2016 Purpose

Protocol summary

Summary

The present study aims to determine the effect of The impact of educational package on level of anxiety and also on hemodynamic status in patients waiting for diagnostic and therapeutic electrophysiological interventions. Method: This clinical trial study conducted on patients awaiting for electrophysiological interventions admitted to Afshar educational-therapeutic center in Yazd consists of Inclusion criteria: The ability to communicate orally ;The ability to understand the Persian language; No history of previous catheterization. Exclusion criteria: Lack of awareness of time, place and identity. 50 Samples were selected through convenience method and were allocated by random block method into two matched group named intervention (received usual care and educational package) and control (received usual care only) groups. Data was collected using three parts questionnaire including personal/clinical data, hospital anxiety and depression scale (only anxiety Part) and hemodynamic chart through interview and records observation and measurement. Personal/clinical data was collected one day before electrophysiology intervention and anxiety levels and hemodynamic status data was collected in two-phases: 1 –phase one day before electrophysiology and 2-phase30 min before electrophysiology intervention. In Intervention group the patient Received package including educational pamphlet, Training videos of patient preparation ablation procedure and oral Description was presented in a meeting of 20 minutes. research assumptions were The impact of educational package effective on anxiety and hemodynamic measures.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021832634N1**
Registration date: **2017-05-28, 1396/03/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-28, 1396/03/07

Registrant information

Name

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Name of organization / entity

Shahid Sadoughi University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

Research deputy of Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of multimodal program on anxiety and hemodynamic status in Patients undergoing electrophysiologic interventions in Afshar hospital in Yazd, 2016 Purpose

Public title
Study of the impact of educational package on anxiety and hemodynamic status in Patients undergoing electro physiologic interventions at Afshar hospital in Yazd, 2016 .

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: The ability to communicate orally; The ability to understand the persian language; No history of previous catheterization (According to the patient); Signed consent. Exclusion criteria: history of mental illness;taking Anti-anxiety drugs and sedatives; Lack of awareness of time, place and identity. loss Criteria: absence of Patients in the ablation; ablation cancellation.

Age
From **17 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

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 of Yazd University of Medical Sciences and Health Services

Street address
Yazd School of Nursing & Midwifery, Bu Ali St., Timsar Falahi Ave., Safaeyeh

City
Yazd

Postal code
8916877443

Approval date
2016-10-24, 1395/08/03

Ethics committee reference number
IR.SSU.REC.1395.133

Health conditions studied

1

Description of health condition studied
Cardiac arrhythmia

ICD-10 code
I47, I48

ICD-10 code description
Paroxysmal tachycardia- Atrial fibrillation and flutter

Primary outcomes

1

Description
The average reduction in anxiety scores

Timepoint
Two phases: previous day of surgery and half an hour before procedure

Method of measurement
Interviews with hospital anxiety and depression questionnaire

Secondary outcomes

1

Description
The average reduction in hemodynamic indices

Timepoint
Two phases: previous day of surgery and half an hour before procedure

Method of measurement
Measure and record the work sheet values of hemodynamic parameters

Intervention groups

1

Description
In the intervention group, Patients received packages including educational pamphlet, film and oral description, in a 20-minute meeting in a room dedicated for this purpose. the researcher explained the goals of interventional electrophysiology diagnosis and treatment, preparation before and care after procedure, and the things that people will see, hear and probably feel.At the same session a film played for the purpose of patient preparation and correct position in bed after ablation. The questions and confusion of patients were answered. Previous day of surgery and half an hour before the procedure, anxiety and vital signs of patients controlled and recorded.

Category

Other

2

Description
In the control group patients received usual care and on the previous day of surgery and half an hour before the procedure, anxiety and vital signs of patients controlled and recorded.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Afshar Hospital
Full name of responsible person
Dadmehr Maryam
Street address
Yazd School of Nursing & Midwifery, Bu Ali St., Timsar Falahi Ave., Safaeyeh,
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadoughi University of Medical Sciences and Health Services
Full name of responsible person
Mehrparvar Hooshang
Street address
Bahonar square, Shahid Sadoughi University of Medical Sciences and Health Services,Yazd
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadoughi University of Medical Sciences and Health Services
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Sadoughi University Medical Sciences Yazd, School of Nursing & Midwifery
Full name of responsible person
Dadmehr Maryam
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Critical Care Nursing Master Science Student
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty