

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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

Maryam Dadmehr

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

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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

Mehrpavar 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

Position

Critical Care Nursing Master Science Student

Other areas of specialty/work

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Position

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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