

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Benson muscle relaxation techniques on anxiety and hemodynamic status in Patients undergoing electrophysiologic interventions

Protocol summary

Summary

The present study aimed to determine the effect of Benson muscle relaxation on level of anxiety and hemodynamic status in patients waiting for diagnostic and therapeutic electrophysiological interventions. Method: This is a clinical trial study with Inclusion Criterias of Minimum age of 18 years old;ability to communicate verbally;Ability to understand the Persian language and recorded issuea on CD;no hearing problems,muscle paralysis,thyroid function disorders,mental illness(according to the patient's report);no previous history of catheter Ablation;lack of experience and familiarity with similar periods of muscle relaxation;sign a written informed consent; and exclusion criterias of transforming for electrophysiological studies sooner than planned time;the lack of compliance with the timeframe specified for relaxation exercises;any changes in treatment plan such as canceling or delay;using sedative drugs over 5 hours before electrophysiology intervention;lack of training relaxation less than three times or not enough exercise accordance with instructions by patient`s report, that was conducted on patients awaiting for electrophysiological interventions admitted to Heshmat educational-therapeutic center in Rasht. 72 Samples were selected through convenience method and were allocated by random block method into two matched group named intervention (usual care and relaxation) and control (usual care only) groups. Data was collected using a three 3 part 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 data were collected in 3-5 hours before electrophysiology intervention and anxiety levels and hemodynamic status collected in two-phase of 3-5 hours and 5-60 min before electrophysiology intervention.

Intervention group were encouraged to listen to audio instructions of Benson relaxation for 10 minutes using headphones, and exercise it at least 3 times between two steps of study. research assumptions were relaxation affects on anxiety and hemodynamic measures reduction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403031118N2**

Registration date: **2015-02-04, 1393/11/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-04, 1393/11/15

Registrant information

Name

Mojgan Baghaie Lakeh

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Social Determinants Of Health Research Center

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2014-05-31, 1393/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Benson muscle relaxation techniques on anxiety and hemodynamic status in Patients undergoing electrophysiologic interventions

Public title

Effect of Benson muscle relaxation techniques on anxiety and hemodynamic status in Patients undergoing electrophysiologic interventions in Dr. Heshmat hospital in Rasht, 2013

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria :Hospitalized patients for electrophysiologic interventions with at least age of 18 years old;ability to communicate verbally;Ability to understand the Persian language and recorded issues on CD;no hearing problems,muscle paralysis,thyroid function disorders,mental illness(according to the patient's report);no previous history of catheter Ablation;lack of experience and familiarity with similar periods of muscle relaxation;sign a written informed consent
Exclusion criteria : transforming for electrophysiological studies sooner than planned time;the lack of compliance with the time frame specified for relaxation exercises;any changes in treatment plan such as canceling or delay;using sedative drugs over 5 hours before electrophysiology intervention;lack of training relaxation less than three times or not enough exercise accordance with instructions by patient's report.

AgeFrom **18 years** old to **90 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **72****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**

Guilan University of Medical Science

Street address

Shahid Beheshti Bolv, Guilan University of Medical Science

City

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Approval date

2014-03-17, 1392/12/26

Ethics committee reference number

2920452602

Health conditions studied**1****Description of health condition studied**

Arrhythmia

ICD-10 code

147-148

ICD-10 code description

Paroxysmal tachycardia-Atrial fibrillation and flutter

Primary outcomes**1****Description**

reduction of anxiety mean score

Timepoint

Two-stage with at least 2 hours apart

Method of measurement

Interview by Using a HAD questionnaire

Secondary outcomes**1****Description**

reduction of hemodynamic measures mean

Timepoint

Two stages with at least 2 hours apart

Method of measurement

measurement and Record on special hemodynamic parameters form chart

Intervention groups

1

Description

The intervention groups: the intervention group will ask for listening a 7-minute relaxation training Audio CD prepared by a qualified professional by a headphone in about 3 -5 hours before performing the electrophysiologic study and practice the technique in accordance with instructions in the tape , at least 3 times with 45 minutes apart under researcher supervision. until 15-60 minute before procedure

Category

Prevention

2

Description

Control group: This group will receive only routine care provided by health care team in 3-5 hours before electrophysiologic intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Therapeutic educational center of DR Heshmat

Full name of responsible person

Mojgan Baghaie Lakeh

Street address

Therapeutic educational center of DR Heshmat,
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City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Social Determinants Of Health Research Center,
Guilan University Of Medical Science,Rasht,Iran.

Full name of responsible person

Mojgan Baghaie Lakeh

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Social Determinants Of Health Research Center,
Nursing & Midwifery College, Daneshju St.,, Shahid
Beheshti BOLV,

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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

Social Determinants Of Health Research Center, Guilan
University Of Medical Science,Rasht,Iran.

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

Social Determinants Of Health Research Center,
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Full name of responsible person

Mojgan Baghaie Lakeh

Position

Master degree. Faculty Member

Other areas of specialty/work

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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