

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The Effect of massage therapy on anxiety of patient's undergoing Electro-Physiology

Protocol summary

Summary

The aim of this study is to evaluate the effect of massage therapy on anxiety levels of patients undergoing cardiac Electro-Physiology. This study is a clinical trial with control conducting in Shahid Faghihi and Kowsare hospital affiliated with Shiraz University of Medical Sciences from Nov, 2016 to Jan, 2016 , Eighty eligible patients candidate for Cardiac Electrophysiology after having obtained the written consent included in study. The patients are selected by convenience sampling and then they are randomly allocated to experimental and control groups. The level of state and trait anxiety were assessed using the Spielberger questionnaire in the all patients before the procedure . The patients in the experimental group receive back massage for 20 minutes. Then after 10 minutes of massage the patient's anxiety level is measured. Finally the anxiety levels of patient before and after the intervention are compared. During this time control group will receive the usual care and questionnaire was completed by them two times in 30 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410278505N11**

Registration date: **2017-01-25, 1395/11/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-25, 1395/11/06

Registrant information

Name

Seyed Saeed Najafi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellery for research affairs

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of massage therapy on anxiety of patient's undergoing Electro-Physiology

Public title

The Effect of therapeutic massage on anxiety of patient's undergoing cardiac Electro-Physiology

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Willingness to participate in research, The Cardiologist has recognized the necessity of undergoing Electrocardiography, Ability to read and write, Having Hemodynamic stability, Age more than 15 years old, Obtaining 31 points or higher from Spielberger anxiety questionnaire Exclusion criteria: History of a known mental illness or taking psychiatric drugs, History

of participation in training courses of problem solving skill and stress Management: History of new crisis such as death of first degree relatives, Divorce of the patient or his/her parents in the last 6 months, Suffering from hearing lossr, Taking sedative and analgesic drugs three hours before the intervention, Drug addiction, Having pain the pre-procedure pain , Reluctance and unwillingness to tacking massage.

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Shiraz University of Medical Sciences

Street address

Zand Blvd, 7 th floor, Shiraz University of Medical Sciences, Shiraz, Iran

City

Shiraz

Postal code

7134814336

Approval date

2016-06-26, 1395/04/06

Ethics committee reference number

IR.SUMS.REC.1395.58

Health conditions studied

1

Description of health condition studied

Atrial Fibrillation

ICD-10 code

I48.1

ICD-10 code description

Persistent Atrial Fibrillation

Primary outcomes

1

Description

Anxiety

Timepoint

Before intervention and after 10 minutes of massage

Method of measurement

Spielberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The control group receives routine care

Category

Lifestyle

2

Description

Massage is done in intervention group in period 20 minutes before the procedure

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar hospital Shiraz

Full name of responsible person

Aliakbar Barzegar

Street address

Western lowland, Shiraz, Iran

City

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2

Recruitment center

Name of recruitment center

Shahid Faghihi Hospital

Full name of responsible person

Aliakbar Barzegar

Street address

Karim Khan Zand Boulevard, Shahid Faghhi hospita, Shiraz, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellery for research affairs

Full name of responsible person

Dr Sayed Basir Hashemi

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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

Vice chancellery for research affairs

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

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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