

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of right and left ventricular size and function using echocardiography in adults, one month and six months after percutaneous atrial septal defect (ASD) closure

Protocol summary

Study aim

Due to the importance of evaluating ventricular function after ASD closure and also due to the fact that studies in this case are limited and incomplete, especially in adults, we decided to evaluate the size and function of the right and left ventricles using echocardiography in adults at one month and six months after percutaneous ASD closure.

Design

clinical trial without control group, non-randomized, on 30 patients, followed for 6 months

Settings and conduct

In this study, 30 patients whose ASD was closed by percutaneous method and who are over 18 years old and willing to participate in the study are examined. A checklist is designed for all participants in the study, which includes demographic information and echocardiographic data before the intervention and the date of the percutaneous intervention. Patients are then followed up for a period of 6 months.

Participants/Inclusion and exclusion criteria

All adult patients who refer to Chamran Hospital for ASD closure and are treated with percutaneous method. Inclusion criteria: 1. Patients whose ASD is closed by the percutaneous method. 2. Patients who are willing to participate in the study. 3. Patients over 18 years of age. 4. Have preoperative echocardiography. 5. Absence of concomitant heart defects Exclusion criteria: 1. Patients who are not willing to participate in further study.

Intervention groups

The intervention group will undergo ASD closure intervention percutaneously. Then, the size and function of the left and right ventricles are evaluated as an indicator of the effectiveness of the intervention.

Main outcome variables

Basal size; Middle size; longitudinal size; left ventricular output; Left ventricular volume; Diastolic dysfunction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210426051085N1**

Registration date: **2021-05-03, 1400/02/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-03, 1400/02/13**

Update count: **0**

Registration date

2021-05-03, 1400/02/13

Registrant information

Name

Fateme Jalalidil

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 4333 8356

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-01, 1400/02/11

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of right and left ventricular size and function using echocardiography in adults, one month and six months after percutaneous atrial septal defect (ASD) closure

Public title

Evaluation of left and right ventricular size and function after percutaneous atrial septal defect closure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients whose ASD is closed by percutaneous method. Patients who consent to participate in the study. Absence of concomitant heart defects Patients older than 18 years Have preoperative echocardiography.

Exclusion criteria:

Patients who tend to leave the study at any stage.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan university of medical sciences, Hezar jerib Ave.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-10-04, 1399/07/13

Ethics committee reference number

IR.MUI.MED.REC.1399.576

Health conditions studied

1

Description of health condition studied

Atrial septal defect

ICD-10 code

Q21.1

ICD-10 code description

Atrial septal defect

Primary outcomes

1

Description

basal size

Timepoint

Before intervention, immediately after intervention, one month after intervention and 6 months after intervention

Method of measurement

Ecocardiography

2

Description

Middle size

Timepoint

Before intervention, immediately after intervention, one month after intervention and 6 months after intervention

Method of measurement

Ecocardiography

3

Description

Longitudinal size

Timepoint

Before intervention, immediately after intervention, one month after intervention and 6 months after intervention

Method of measurement

Ecocardiography

4

Description

Left ventricle output

Timepoint

Before intervention, immediately after intervention, one month after intervention and 6 months after intervention

Method of measurement

Ecocardiography

5

Description

Left ventricle volume

Timepoint

Before intervention, immediately after intervention, one month after intervention and 6 months after intervention

Method of measurement

Ecocardiography

6**Description**

Diastolic dysfunction

Timepoint

Before intervention, immediately after intervention, one month after intervention and 6 months after intervention

Method of measurement

Ecocardiography

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients undergoing ASD percutaneous closure

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Chamran Hospital

Full name of responsible person

Reyhaneh Zavar

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Cardiology department, Chamran Hospital, Salman Farsi Ave

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Web page address

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Grant name**Grant code / Reference number**

399007

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Fateme Jalali

Position

Resident

Latest degree

Medical doctor

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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

It will be presented as supplementary data in the article

When the data will become available and for how long

Access at the same time as the article is published

To whom data/document is available

Whole people

Under which criteria data/document could be used

Individuals and organizations should coordinate with the scientific director of this study if they need to use or analyze the data

From where data/document is obtainable

The scientific director of this study

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

It can be used after approval by the scientific director of the study

Comments