

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Determination and comparison of right and left ventricular function by speckle tracking in children before and after percutaneous atrial septal defect (ASD) closure.

Protocol summary

Study aim

Determination and comparison of right and left ventricular function using speckle tracking in children before and after percutaneous atrial septal defect (ASD) closure.

Design

Clinical trial with control group, 26 patients, with parallel groups-Non-randomized

Settings and conduct

Patients with atrial septal defect before, one day and one month after closure of this defect are evaluate at Imam Hossein Hospital in Isfahan by Speckle Tracking.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: age less than 18 years, having detected the atrial septal defect, satisfaction of the parent or the patient himself to participate in this study, Not having complex cardiac defects

Intervention groups

Intervention group : children with atrial septal defect less than 18 years of age that had atrial septal defect closure percutaneously had evaluated before and after procedure by Speckle Tracking. Control group: in control group Speckle Tracking estimated one time for comparison.

Main outcome variables

ventricular function

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20170801035441N2**

Registration date: **2018-10-20, 1397/07/28**

Registration timing: **retrospective**

Last update: **2018-10-20, 1397/07/28**

Update count: **0**

Registration date

2018-10-20, 1397/07/28

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3335 5881

Email address

m.ghaderian@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

2017-06-22, 1396/04/01

Actual recruitment end date

2018-03-21, 1397/01/01

Trial completion date

2018-09-22, 1397/06/31

Scientific title

Determination and comparison of right and left ventricular function by speckle tracking in children before and after percutaneous atrial septal defect (ASD) closure.

Public title

Using of Speckle Tracking in atrial septal defect closure in pediatric

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Age under 18 years Having an atrial septal defect which diagnosed by a pediatric cardiologist and has indication for closure. Consent of the parent or the patient to participate in this study do not have complex heart defects.

Exclusion criteria:

Age

To **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **26**

Actual sample size reached: **26**

Randomization (investigator's opinion)

Not 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 Esfahan University of Medical Sciences

Street address

Esfahan University of Medical Science, Azadi Square, Hezar Jerib st

City

Esfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2017-11-29, 1396/09/08

Ethics committee reference number

IR.MUI.REC.1396.3.721

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

ventricular function

Timepoint

Before, one day and one month after atrial septal defect closure

Method of measurement

Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Interventional group: Patients who have been treated percutaneously using Occlutech Amplatzer (made in Germany) that had prepared are included in this study. This procedure performed in angiography operation room from femoral vein and Amplatzer implanted in the defect from this vein and standard approach and the defect resolved. Cardiac function in these patients is evaluated by Speckle Tracking V7 Samsung echocardiography (made in Korea) . This method could evaluate cardiac function regionally and globally.

Category

Diagnosis

2

Description

Control group: The equal number of healthy children who were matched with the control group were examined by echocardiography and compared with the intervention group.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hosein hospital

Full name of responsible person

Mehrdad Memarzade

Street address

Emam Hosein hospital, Emam Khomeini street

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emamhossein_hospital@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjouye Javanmard

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Fax

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sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Mehdi Ghaderian

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

Contact

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data after unrecognizable person

When the data will become available and for how long

One year after study

To whom data/document is available

The data is available to researchers working in medical sciences

Under which criteria data/document could be used

Persons who working in pediatric cardiology and echocardiography

From where data/document is obtainable

+989131004787 Mehdi Ghaderian

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

After telephone and confirmation, data will be transferred.

Comments

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