Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 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

Isfehan

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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Email
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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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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
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Person responsible for updating data

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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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