

# 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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8195100000

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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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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

**Street address**

no. 34, alley no. 16, Chaharbaghe Paein st

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Email**

Ghader\_45@yahoo.co.uk

**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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