

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of safety and efficacy of dual-coil and single coil leads in patients with implantable cardioverter-defibrillator

#### Protocol summary

##### Summary

The aim of this study is to compare efficacy and safety of single coil versus dual coil defibrillation leads in patients with implantable cardioverter-defibrillator (ICD). Patients with a standard ICD indications are included in the study. Patients are excluded if they had ventricular arrhythmia due to a reversible cause, a life expectancy < 12 months due to other medical conditions, or had a tricuspid valve prosthesis. During two years, a total of 100 patients are randomly allocated to treatment with single coil or dual coil ICD leads. All leads were implanted transvenously using the subclavian or cephalic vein via a 9 Fr introducer. Pulse generators were implanted pectorally. Primary outcome is lead pacing parameters and defibrillation threshold testing (DFT) at implant. Secondary outcomes are number of successful ICD interventions, mortality related to high DFT, and lead complications.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201202011965N3**

Registration date: **2012-06-28, 1391/04/08**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-06-28, 1391/04/08

##### Registrant information

###### Name

Majid Haghjoo

###### Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2392 2163

###### Email address

majid.haghjoo@gmail.com

###### Recruitment status

**Recruitment complete**

###### Funding source

Tehran University of Medical Sciences

###### Expected recruitment start date

2012-04-20, 1391/02/01

###### Expected recruitment end date

2014-01-20, 1392/10/30

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Comparison of safety and efficacy of dual-coil and single coil leads in patients with implantable cardioverter-defibrillator

###### Public title

Safety and efficacy of dual-coil and single coil implantable cardioverter-defibrillator leads

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: Standard indications for implantable cardioverter-defibrillator implantation and Exclusion criteria: ventricular arrhythmia due to a reversible cause; life expectancy < 12 months due to other medical conditions; tricuspid valve prosthesis; redo procedure

###### Age

From **15 years** old to **80 years** old

###### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 200

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Rajaei cardiovascular medical & research center

##### Street address

Vali-Asr, Niayesh

##### City

Tehran

##### Postal code

#### Approval date

2012-06-09, 1391/03/20

#### Ethics committee reference number

90-04-14-15889-54415

## Health conditions studied

### 1

#### Description of health condition studied

Cardioversion-Defibrillation

#### ICD-10 code

I46.0

#### ICD-10 code description

Cardiac arrest with successful resuscitation

## Primary outcomes

### 1

#### Description

Lead pacing paramters and defibrillation threhsold testing

#### Timepoint

1, 6, and 12 months

#### Method of measurement

Programmer

## Secondary outcomes

### 1

#### Description

Number of successful ICD interventions, mortality related to high DFT, and lead complications

#### Timepoint

1, 6, and 12 months

#### Method of measurement

History, physical exam, chest x-ray, and programmer

## Intervention groups

### 1

#### Description

Single coil defibrillation leads: defibrillator lead with single coil located in the distal portion of the lead. In this setting, distal RV coil serves as anode and Active Can as cathode.

#### Category

Treatment - Devices

### 2

#### Description

Dual coil defibrillation leads: defibrillator lead with both proximal and distal coils. In this configuration, distal coil serves as anode and Active Can-proximal SVC coil serves as cathode

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rajaie Cardiovascular Medical Center

##### Full name of responsible person

Majid Haghjoo

##### Street address

Vali-e-Asr St., Mellat Park

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Fotoohi

##### Street address

Tehran University of Medical Sciences, Ghods St, Keshavarz Ave

**City**  
Tehran

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**  
Vice chancellor for research, Tehran University of Medical Sciences

**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**  
Cardiac Electrophysiology Research Center

**Full name of responsible person**  
Dr. Majid Haghjoo

**Position**  
Research vice chancellor/ Associate professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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Cardiac Electrophysiology Research Center

**Full name of responsible person**  
Dr. Majid Haghjoo

**Position**  
Research vice chancellor/Associate Professor

**Other areas of specialty/work**

**Street address**  
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majid.haghjoo@gmail.com

**Web page address**  
<http://www.rhc.ac.ir/>

## Person responsible for updating data

**Contact**

**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*