Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 withsingle 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
Street address
Vali-e-Asr St., Mellat Park
City
Tehran
Postal code
1996911151
Phone
+98 21 2392 2163
Fax
+98 21 2237 4288
Email
majid.haghjoo@gmail.com
Web page address
http://www.rhc.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Cardiac Electrophysiology Research Center
Full name of responsible person
Dr. Majid Haghjoo
Position
Research vice chanceller/Associate Professor
Other areas of specialty/work
Street address
Vali-e-Asr St., Mellat Park
City
Tehran
Postal code
1996911151
Phone
+98 21 2392 2163
Fax
+98 21 2237 4288
Email
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