Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparing Effectiveness and Safety of Synchronized Electrical Cardioversion by ZOLL and SAIRAN Electroshocks in Patients with Atrial Fibrillation: A Non-Inferiority Double Blinded Randomized Clinical Trial

Protocol summary

Study aim
Comparing Effectiveness and Safety of Synchronized Electrical Cardioversion by ZOLL and SAIRAN Electroshocks in Patients with Atrial Fibrillation: A Non-Inferiority Double Blinded Randomized Clinical Trial

Design
A concealed, randomized, single blinded, controlled clinical trial with a parallel group design of 671 patients

Settings and conduct
Setting of study: Chamran Heart Center, Isfahan, Iran Type of randomization: Block randomization (block size = 4). Blinding: double blinded (patient and data analyser will be blinded)

Participants/Inclusion and exclusion criteria
Inclusion criteria: Atrial fibrillation; Definite candidate for Synchronized Electrical Cardioversion to restore AF rhythm to sinus rhythm; and Satisfaction Non-inclusion criteria: Problematic disorders (advanced cancers, severe kidney problems (Glomerular filtration rate <30), liver problems, etc) and Not having the necessary conditions for Synchronized Electrical Cardioversion

Intervention groups
1 Intervention group: patients treated by SAIRAN Electroshock; control group: 2 patients treated by Zoll Electroshock. Intervention in this study is performing Electrical Cardioversion in patients with atrial fibrillation to change their cardiac rhythm from fibrillation state to sinus state. Patients will be randomly assigned to one of aforementioned groups and treated by Electroshock.

Main outcome variables
status of cardiac rhythm after electroshock

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190608043836N1**
Registration date: **2019-08-22, 1398/05/31**
Registration timing: **prospective**

Last update: **2019-08-22, 1398/05/31**
Update count: **0**

Registration date
2019-08-22, 1398/05/31

Registrant information

Name
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Name of organization / entity
Interventional Cardiology Research Center, Cardiovascular Research institute, Isfahan University of

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2025-03-19, 1403/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing Effectiveness and Safety of Synchronized Electrical Cardioversion by ZOLL and SAIRAN Electroshocks in Patients with Atrial Fibrillation: A Non-Inferiority Double Blinded Randomized Clinical Trial

Public title
Inferiority of ZOLL and SAIRAN Electroshocks
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Atrial fibrillation Definite candidate for Synchronized Electrical Cardioversion to convert cardiac rhythm from atrial fibrillation to sinus rhythm Satisfaction
Exclusion criteria:
complicated disorders (advanced cancers, severe kidney problems (Glomerular filtration rate <30), liver problems, etc) Lack of necessary conditions for Synchronized Electrical Cardioversion
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **670**
Randomization (investigator's opinion)
Randomized
Randomization description
Block Randomization (block size=4) is used for random allocation of patients. Using RANDBETWEEN command in excell program, we determined sequence of blocks. With a sample and block size 670 and 4, respectively, RANDBETWEEN will be run for 168 times. After determining sequence of all blocks, a patient-specific 5-digits code will be written on a paper. Then paper is folded and put in a dark and thick sealed envelop. Envelops will be numbered from 1 to 670 according to blocks sequences. The meaning of 5-digits code will not be clear for patients so we will have concealment. only assessors (physician) who open envelop will be informed that how they distinguish the brand of device (Salran or Zoll). A trained and blind nurse will preserve sealed envelops securely and deliver them to assessor (physician) one at the time according to numbering on it. For example, when first patient enters to study, the first envelope, numbered 1 on it, is delivered by the responsible nurse to the physician. Physician will open it and select type of electroshok device for patient based on 5-digits code. This work will be repeated until last patient.
Blinding (investigator's opinion)
Double blinded
Blinding description
There is no possibility for blinding of assessors (physicians) due to the fact that the Zoll is known to all. However, patients will be blinded via masking device brand. In addition, we will blind data analyser. So this will be a double blinded study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Floor 2, Bleeding No.4, Isfahan University of M Hezarjerib Street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2019-05-28, 1398/03/07
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.125

Health conditions studied

1

Description of health condition studied
Atrial Fibrillation
ICD-10 code
I48
ICD-10 code description
Atrial fibrillation and flutter

Primary outcomes

1

Description
cardiac rhythm status after electroshock
Timepoint
As soon as it occurs after starting the intervention
Method of measurement
Monitoring of cardiac rhythm

Secondary outcomes

1

Description

The number of shocks performed to achieve success (sinus cardiac rhythm)

Timepoint

After starting intervention

Method of measurement

counting and recording in questionnaire

2

Description

Energy consumed to achieve success

Timepoint

After starting intervention

Method of measurement

observing device monitor and recording in questionnaire

3

Description

Needing to use a temporary pacemaker to adjust the heart rate after performing a shock

Timepoint

After starting intervention

Method of measurement

questionnaire

4

Description

Heart pulses marked correctly

Timepoint

After starting intervention

Method of measurement

questionnaire

5

Description

skin burning at electrodes spots

Timepoint

in 12th and 24th hour after intervention

Method of measurement

observing and recording in questionnaire

6

Description

severity of skin burning at electrodes spots

Timepoint

in 12th and 24th hour after intervention

Method of measurement

observing and recording in questionnaire

7

Description

Burn wound area

Timepoint

in 12th and 24th hour after intervention

Method of measurement

observing and recording in questionnaire

8

Description

Thromboembolic events after Electroshock

Timepoint

in 12th and 24th hour after intervention

Method of measurement

observing and writing in questionnaire

Intervention groups

1

Description

Intervention group: Group treated by Electroshock of Sa-Iran. Before the shock, the first part of the questionnaire, which includes demographic data and risk factors, is completed by the patient's nurse. Then patient is allocated to Sa-Iran or Zoll group. After randomizations, the patient is prepared for the shock. The patient's nurse completes the second part of the questionnaire, which includes shock data (number of shocks performed to achieve success, number of used paddles, etc.) under supervision of physician. Patients is followed up at least for 24 hours after procedure in hospital. Patient's nurse completes the third part of the questionnaire, which includes complications data (thrombotic events, Burn wound status, etc.) in 12 and 24 hours after performing shock.

Category

Treatment - Devices

2

Description

Control group: group treated by Electroshock of Zoll. Before the shock, the first part of the questionnaire, which includes demographic data and risk factors, is completed by the patient's nurse. Then patient is allocated to Sa-Iran or Zoll group. After randomizations, the patient is prepared for the shock. The patient's nurse completes the second part of the questionnaire, which includes shock data (number of shocks performed to achieve success, number of used paddles, etc.) under supervision of physician. Patients is followed up at least for 24 hours after procedure in hospital. Patient's nurse completes the third part of the questionnaire, which includes complications data (thromboembolic events, Burn wound status, etc.) in 12 and 24 hours after performing shock.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Heart Center, Isfahan, Iran

Full name of responsible person

Dr.Alireza Khosravi

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Chamran Heart Center, Shahid Rahmani Alley, Moshtagh Sevom Steet, Isfahan, Iran.
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Sairan medical company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Interventional Cardiology Research Center, Cardiovascular Research institute, Isfahan University of
Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is not more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available