Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Efficacy and safety of the Defibrillator / Monitor model Re-pulse6 Avecinna Co. among patients with atrial fibrillation and flutter who are candidates of elective cardioversion: a stratified non-inferiority randomized controlled trial at Tehran Heart Center

Protocol summary

Study aim
Efficacy and safety of the Defibrillator / Monitor model Re-pulse 6 Avecinna Co. among patients with atrial fibrillation and flutter who are candidates of elective cardioversion

Design
The study will be a non-inferiority randomized clinical trial with a parallel, single center, stratified, and without blinding design. 70 patients will be in the intervention group and 35 in the control group.

Settings and conduct
There will be no blinding. Study will be performed in Tehran heart center.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age >18 years old; atrial fibrillation or flutter; indication for cardioversion; atrial fibrillation or flutter will be confirmed by an electrophysiologist using 12 lead standard ECG. Cardioversion will be conducted at the discretion of the electrophysiologist. All patients are required to receive at least 4 weeks of antio coagulation or left atrial thrombus is ruled out by trans esophageal echocardiography. Exclusion criteria: requiring emergency cardioversion; hemodynamic instability; chest pain or suspicion of acute coronary syndrome; hypokalemia; digoxin toxicity; pregnancy or breastfeeding; no informed consent

Intervention groups
Repulse 6 (experimental) and standard LIFE PACK20

Main outcome variables
Success in producing sinus rhythm

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230809059099N2**
Registration date: **2024-03-01, 1402/12/11**
Registration timing: **prospective**

Last update: **2024-03-01, 1402/12/11**
Update count: **0**

Registration date
2024-03-01, 1402/12/11

Registrant information

Name
Farzad Masoudkabir

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8802 9600

Email address
farzad.masoudkabir@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-05, 1402/12/15

Expected recruitment end date
2025-12-21, 1404/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy and safety of the Defibrillator / Monitor model Re-pulse6 Avecinna Co. among patients with atrial

fibrillation and flutter who are candidates of elective cardioversion: a stratified non-inferiority randomized controlled trial at Tehran Heart Center

Public title
Efficacy and safety of Iranian Avecinna co. defibrillator
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age >18 years old Atrial fibrillation or flutter indication for cardioversion Atrial fibrillation or flutter will be confirmed by an electrophysiologist using 12 lead standard ECG. Cardioversion will be conducted at the discretion of the electrophysiologist. All patients are required to receive at least 4 weeks of antio coagulation or left atrial thrombus is ruled out by trans esophageal echocardiography
Exclusion criteria:
Requiring emergeny cardioversion Hemodynamic instability Chest pain or suspicion of acute coronary syndrome Hypokalemia Digoxin toxicity Pregnancy or breastfeeding No informed consent
Age
From **18 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomized using stratified method to re-pulse6 and standard defibrillator (Life Pack 20) groups. randomization code will be assigned after the patient is officially enrolled in the study and there will be no blinding.
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
Tehran University of Medical Sciences, Ethics Committee
Street address
Department of Cardiovascular Research, Tehran Heart Center, North Kargar Ave, Tehran,
City
tehran
Province
Tehran
Postal code
1411713138
Approval date
2023-08-06, 1402/05/15
Ethics committee reference number
IR.TUMS.THC.REC.1402.043

Health conditions studied

1

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

Primary outcomes

1

Description
Rate of sinus rhythm conversion
Timepoint
After cardioversion
Method of measurement
ECG

Secondary outcomes

1

Description
Number of times shock is required in experimental and standard device
Timepoint
After start of the cardioversion process
Method of measurement
Number

2

Description
Safety: any inflammation, burn, pain, or electrocution in experimental device compared to standard device. comparison of ventricular arrhythmias, bradycardia, or asystole.comparison of any other adverse effects
Timepoint
Immeadiately after shock
Method of measurement
Observation by the cardiologist

Intervention groups

1

Description

Intervention group: Avecinna defibrillator. In both groups patients will be sedated. antiarhythmic drug use will be recorded in CRF forms. anti-arrhythmic drugs will not be used as pretreatment in cardiversion. Continuous ECG monitoring will be performed for all patients. In all patients biphasic waves and anteriorleft lateral sticking patches will be used. electrodes will be placed in the anterior in the middle of the sternum and in the posterior in the medial and inferior to the left scapula. in atrial fibrillation patients three biphasic shock waves will be used until the sinus rhythm is achieved. the order of the shocks will be as follows: 100, 200, and 300 joules. In atrial flutter patients three biphasic shock waves will be used until the sinus rhythm is achieved. the order of the shocks will be as follows: 50, 100, and 200 joules. If sinus rhythm is not achieved after three shockwaves treatment failure will be announced. Patients with treatment failure will be removed from the study and their treatment will be based on the cardiologist's discretion. all adverse events and outcomes will be recorded before and after cardioversion.

Category

Treatment - Devices

2

Description

Control group: standard defibrillator (LIFE PACK 20). In both groups patients will be sedated. antiarhythmic drug use will be recorded in CRF forms. anti-arrhythmic drugs will not be used as pretreatment in cardiversion. Continuous ECG monitoring will be performed for all patients. In all patients biphasic waves and anteriorleft lateral sticking patches will be used. electrodes will be placed in the anterior in the middle of the sternum and in the posterior in the medial and inferior to the left scapula. in atrial fibrillation patients three biphasic shock waves will be used until the sinus rhythm is achieved. the order of the shocks will be as follows: 100, 200, and 300 joules. In atrial flutter patients three biphasic shock waves will be used until the sinus rhythm is achieved. the order of the shocks will be as follows: 50, 100, and 200 joules. If sinus rhythm is not achieved after three shockwaves treatment failure will be announced. Patients with treatment failure will be removed from the study and their treatment will be based on the cardiologist's discretion. all adverse events and outcomes will be recorded before and after cardioversion.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Heart center
Full name of responsible person
Farzad Masoud Kabir
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Department of Cardiovascular Research, Tehran Heart Center, North Kargar Ave, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Avecinna co
Full name of responsible person
Matin Motamedi
Street address
Unit 1, No.3, 58th St, Asad Abadi St, (Yousef Abad St)
City
Tehran
Province
Tehran
Postal code
1436864843
Phone
+98 21 8805 4231
Email
export1@avecinna.com

Grant name

Grant code / Reference number

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

Title of funding source
Avecinna co

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

Tehran University of Medical Sciences

Full name of responsible person
Farzad Masoud Kabir

Position
associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Cardiology

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Person responsible for scientific inquiries

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Farzad Masoud Kabir

Position
Associate professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Undecided - It is not yet known if there will be 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

Title and more details about the data/document
only a part of the data such as the primary outcomes will be shared

When the data will become available and for how long
after completion of the study

To whom data/document is available
for scientific community

Under which criteria data/document could be used
documents will be shared upon reasonable request

From where data/document is obtainable
from cardiovascular diseases esearch institute

What processes are involved for a request to access data/document
please email farzad masoudkabir. farzad.masoudkabir@gmail.com

Comments