

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 anticoagulation 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 Masoudkabar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8802 9600

Email address

farzad.masoudkabar@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 anticoagulation 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

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 resuscitate 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.TH.C.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

Immediately after shock

Method of measurement

Observation by the cardiologist

Intervention groups

1

Description

Intervention group: AVECINNA defibrillator. In both groups patients will be sedated. antiarrhythmic drug use will be recorded in CRF forms. antiarrhythmic drugs will not be used as pretreatment in cardioversion. 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. antiarrhythmic drug use will be recorded in CRF forms. antiarrhythmic drugs will not be used as pretreatment in cardioversion. 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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farzad.masoudkabir@gmail.com

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)

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Tehran

Province

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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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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 research institute

What processes are involved for a request to access data/document

please email farzad.masoudkabir.
farzad.masoudkabir@gmail.com

Comments