Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

randomized clinical trial of midodrine effectiveness in patients who underwent open heart surgery and after surgery their mean atrial blood pressure is low despite receiving at least 24 hours intravenous inotrope in Tehran Heart Center in 1399 to 1400

Protocol summary

Study aim

Determination of midodrine prescription effectiveness in decrease time dependency to IV inotrope after midodrine initiation in patient who are dependent to IV inotrope after open heart surgery.

Design

A randomised, parallel group, double blinded, with control group clinical trial, phase 3 on 100 patients.For randomisation used function rand excell software.

Settings and conduct

This study will do in Tehran Heart Center, all patients who under go CABG and at least 24 hours after surgery receive IV inotrope and their blood pressure is low divided to two groups. ICU physician visit all of them and if they have inclusion criteria they enter to study by him. According to excel software patients randomized to A and B groups and ward nurse give patient drug or placebo. Here both physician and nurse don't know which one is drug or placebo and only pharmacy Responsible knows that.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-More than 18 years old 2-Admitted in ICU 3-Systolic blood pressure less than 90 mmHg or mean arterial blood pressure less than 80 mmHg 4-Dependent to IV vasopressor 5-At least 24 hours received IV vasopressor and can't discontinue it 6-CABG operation exclusion criteria: 1-Inadequate tissue oxygenation 2-Liver failure 3-Renal failure (cr>2mg/dl) 4-Pregnancy 5-Pheochromocytoma 6-Thyrotoxicosis 7-Midodrine as pre-admission medication 8-Any known allergies to midodrine 9-Enrollment in another clinical trial

Intervention groups

The patients who are dependent to IV inotrope after CABG surgery divided to two groups, in case group we describe midodrine 5 mg every 12 hours and in control group we describe placebo every 12 hours, finally we follow up the groups and answer this question, Is midodrine elevate blood pressure and discontinue IV inotrope dependency or not?

Main outcome variables

Dependency rate to IV inotrope ICU length of stay Hospital length of stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201025049139N1**
Registration date: **2021-01-15, 1399/10/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-15, 1399/10/26**
Update count: **0**

Registration date

2021-01-15, 1399/10/26

Registrant information

Name

Mostafa Ziaoddini

Name of organization / entity

Country

Iran (Islamic Republic of)

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mostafa_zia@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-10-31, 1399/08/10
Expected recruitment end date
2022-02-20, 1400/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
randomized clinical trial of midodrine effectiveness in patients who underwent open heart surgery and after surgery their mean atrial blood pressure is low despite receiving at least 24 hours intravenous inotrope in Tehran Heart Center in 1399 to 1400

Public title
midodrine effectiveness in patients who have low mean atrial pressure after open heart surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
More than 18 years old Admitted in ICU Systolic blood pressure less than 90 mmHg or mean atrial pressure less than 80 mmHg Dependent to IV vassopressor Received at least 24 hours IV vassopressor and can not discontinue it Operation type is CABG
Exclusion criteria:
hypovolemia septic shock kidney failure (Cr>2mg/dl) hepatic failure electrolyte disturbance pregnancy tamponed active bleeding hypothyroid hyperthyroid midodrine allergy
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Case and control groups are randomized with statistical software (excel), patients who have entrance criteria enter to trial by ICU physician who visit patients every day. After entrance one of ICU nurses divided patients to two groups (A and B) according above list. after division the ICU drug responsible give the patients midodrine or placebo according A or B group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients who visited with ICU physician and have entrance criteria, enter to the study.After that one of nurses according to the list that made by software divide patients to two groups, A and B. According A or B, the nurse give patients A or B drugs. Nurse don't know which one is drug and which one is placebo. All information gather with resident.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Tehran Heart Center, North Karegar, Amir Abad, Tehran
City
Tehran
Province
Tehran
Postal code
1234567890
Approval date
2020-09-14, 1399/06/24
Ethics committee reference number
IR.TUMS.THC.REC.1399.027

Health conditions studied

1

Description of health condition studied
CABG
ICD-10 code
I25.701
ICD-10 code description
Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm

Primary outcomes

1

Description
blood pressure dependency rate to IV inotrope after midodrine initiation
Timepoint
study entrance time and 48 hours after that
Method of measurement
with Sphygmomanometer

2

Description
intravenous vasopressor dose
Timepoint
after intravenous vasopressor discontinuation
Method of measurement
microgram

3

Description
ICU length of stay
Timepoint
after patient discharge from ICU
Method of measurement
according to hour

4

Description
hospital length of stay
Timepoint
after patient discharge
Method of measurement
according to hour

5

Description
left ventricular function
Timepoint
at the time of randomization
Method of measurement
echocardiography

6

Description
creatinine
Timepoint
at the time of randomization
Method of measurement
in lab

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: we prescribe midodrine 5 mg every 12 hours, after IV inotrope discontinuation we change the dose to 2.5 mg every 12 hours an after 3 days discontinue midodrine
Category
Treatment - Drugs

2

Description
Control group: we prescribe placebo to this group and after IV inotrope discontinuation we continue placebo half dose and after 3 days we discontinue it
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center
Full name of responsible person
Mostafa Ziaoddini
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
Street address
Tehran University of Medical Science, 16 azar street, Inqlab ave, Tehran
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+98 21 6405 3325
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msahrai@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public

Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mostafa Ziaoddini
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data will publish after trial without patient's name.
When the data will become available and for how long
6 months after publishing data until unlimited time
To whom data/document is available
All researchers
Under which criteria data/document could be used
All conditions
From where data/document is obtainable
mostafa_zia@yahoo.com k-hosseinu@tums.ac.ir
What processes are involved for a request to access data/document
send his or her request to above E-mails, in one week we answer the request
Comments