Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Effect of Melatonin on Coronary perfusion after primary percutaneous coronary intervention

Protocol summary

Study aim
The effect of melatonin on coronary perfusion after PPCI in patients with myocardial infarction
Design
Double blinded, controlled randomized trial
Settings and conduct
Patients with STEMI PPCI candidate referred to Modarres Hospital are divided into two groups. Patients in the case group will receive 3 mg of melatonin before PPCI and control group will receive placebo before PPCI without melatonin. The patient is not aware of the type of drug received.Doctors who perform PPCI and those who complete patient information are not informed about the type of medication being taken.
Participants/Inclusion and exclusion criteria
Inclusion criteria: being at least 18 years old; PPCI for the first 6 hours; STEMI evidence in patient electrocardiogram; blockage of one of the major coronary arteries; verbal Desire and Written Patient Satisfaction. Exclusion criteria: ESRD; history of autoimmune diseases; patient with severe illness with short prognosis; atrial fibrilation before or after PPCI; pregnancy or breast feeding.
Intervention groups
Case groupe will receive 3 mg of melatonin before PPCI and the control group will receive PPCI without melatonin
Main outcome variables
Changes in coronary artery perfusion

General information

Reason for update
Acronym
MCP
IRCT registration information
IRCT registration number: **IRCT20191214045726N1**
Registration date: **2020-01-15, 1398/10/25**
Registration timing: **prospective**
Last update: **2020-01-15, 1398/10/25**
Update count: **0**
Registration date
2020-01-15, 1398/10/25

Registrant information
Name
zahra alipour
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-01-21, 1398/11/01
Expected recruitment end date
2021-01-20, 1399/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Melatonin on Coronary perfusion after primary percutaneous coronary intervention

Public title
Effect of Melatonin on Coronary perfusion after primary percutaneous coronary intervention
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Acute Myocardial infarction Age older than 18 years old PPCI for the first 6 hours STEMI evidence in patient electrocardiogram Blockage of one of the major coronary arteries Verbal desire and written patient satisfaction to participate in the study

Exclusion criteria:

Chronic renal failure A history of autoimmune disease Atrial fibrilation Pregnancy or breast feeding

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients randomly assigned in 1:1 rathio and the computer is classified into two groups of case and control

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

Ethics Committee of Biomedical Research Vice Chancellor for Research of Shahid Beheshti University o

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7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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Approval date

2019-11-03, 1398/08/12

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.371

Health conditions studied

1

Description of health condition studied

Myocardial infarction

ICD-10 code

I21.3

ICD-10 code description

ST elevation (STEMI) myocardial infarction of unspecified site

Primary outcomes

1

Description

Changes in coronary artery perfusion

Timepoint

Determination of coronary perfusion before PPCI and within 40 days after PPCI

Method of measurement

Angiography and echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 3 mg melatonin given to patients with myocardial infarction before PPCI instead of melatonin.

Category

Treatment - Drugs

2

Description

Control group: patients with myocardial infarction who receive placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Modarres hospital

Full name of responsible person

Zahra Alipur

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

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Grant name
Clinical Research Development Center, Shahid Modarres Educational hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Vahid Eslami

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Cardiology

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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
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Not applicable