

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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 fibrillation before or after PPCI; pregnancy or breast feeding.

Intervention groups

Case group 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2208 3106

Email address

z_alipour@yahoo.com

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 fibrillation 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 ratio 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.

City

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Province

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Postal code

19839-63113

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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Web page address

<https://modarres.sbm.ac.ir/>

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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

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Full name of responsible person

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Latest degree

Specialist

Other areas of specialty/work

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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