

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Effects of Low Level Laser Therapy in comparison with laser therapy with none therapeutic power on the complications of Coronary Artery Bypass Surgery in patients with coronary artery stenosis

Protocol summary

Summary

(1) Objectives: Evaluate the efficacy of intravenous and local Laser therapy of on the complications of coronary bypass grafting in patients with coronary artery disease. (2) Design: The study population is patients with stenosis in two or three coronary arteries hospitalized in Shahid Rajaei heart center for coronary bypass grafting. Recruited patients will be divided into two equal groups using block randomization. At least 252 patients will be recruited and the trial will be conducted as single blind, phase three, mono centric trial. (3) Setting and conduct: Intravenous and local laser therapy will be applied for patients who has been randomly selected for intervention groups and laser therapy with none therapeutic power will be applied for control group. Ultimately Intervention and control groups will be compared regarding coronary bypass grafting complications. (4) Participants: Patients with stenosis in their coronary arteries hospitalized for coronary artery bypass grafting without chronic diseases or cancer. (5) Intervention: Intravenous and local laser therapy. (6) Main outcome measures: Pericardial effusion, Fibrillation and Heart Failure.

General information

Acronym

CABG or Coronary Artery Bypass Grafting Low level Laser Therapy or LLLT

IRCT registration information

IRCT registration number: **IRCT2016052926069N4**
Registration date: **2016-08-25, 1395/06/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-25, 1395/06/04

Registrant information

Name

Fereshteh Ansari

Name of organization / entity

Razi Vaccine and Serum Research Institute

Country

Iran (Islamic Republic of)

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Email address

ansarif@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Rajaie Cardiovascular Medical and Research Center, Iran
University of Medical Sciences, Tehran, Iran

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Low Level Laser Therapy in comparison with laser therapy with none therapeutic power on the complications of Coronary Artery Bypass Surgery in patients with coronary artery stenosis

Public title

Effects of Low Level Laser Therapy on the complications of CABG

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with stenosis in two or three coronary arteries (2VD/3VD) candidate for CABG.

Exclusion criteria: renal chronic diseases; Hepatic chronic diseases; Diabetes; Cancer

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **252**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Blocked randomization has been applied for this study.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Heart Center of Shahid Rajaei

Street address

Niayesh Highway Intersection, Valiasr Street, Tehran

City

Tehran

Postal code

1996911151

Approval date

2016-02-27, 1394/12/08

Ethics committee reference number

IHC.AC.IR.REC.1394.36

Health conditions studied**1****Description of health condition studied**

Coronary artery bypass grafting complications

ICD-10 code

-

ICD-10 code description**Primary outcomes****1****Description**

Atrial fibrillation

Timepoint

Before surgery, after surgery, daily until one week

Method of measurement

Electrocardiography, Ecocardiography

2**Description**

Heart Failure

Timepoint

Before surgery, One week after surgery

Method of measurement

Electrocardiography, Ecocardiography

3**Description**

Hypertrophic Scar

Timepoint

3 to 6 months after surgery

Method of measurement

Vancouver Scar Scale Questionnaire

4**Description**

Death

Timepoint

3 to 6 months after surgery

Method of measurement

Reviewing patients medical records

5**Description**

Needing Repetition of CABG

Timepoint

3 to 6 months after surgery

Method of measurement

Reviewing patients medical records

Secondary outcomes**1****Description**

Pericardial effusion

Timepoint

Before surgery, One week after surgery

Method of measurement

Electrocardiography, Ecocardiography

2

Description

Bleeding

Timepoint

48 hours after CABG

Method of measurement

Measuring Suctioned blood

Intervention groups

1

Description

Intervention group: Application of Intravenous and local Low level laser. Intravenous red laser, 655 nm, 1 mW for 15 minutes via cubital vein and local laser, infrared 780 nm, 200 mW, 6 J/Cm² on the incision area and pericardium. Both lasers are used immediately after the surgery and every day after surgery for 7 days

Category

Prevention

2

Description

control group: Application of intravenous and local Laser with none therapeutic power.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular, Medical & Research Center

Full name of responsible person

Nooshafarin Kazemikhoo

Street address

Niayesh Highway Intersection, Valiasr Ave, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran university of medical science (Rajaie Cardiovascular Medical and

Full name of responsible person

Dr. Majid Kiavar

Street address

Niayesh Highway Intersection, Valiasr Street, Tehran

City

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice chancellor for research, Iran university of medical science (Rajaie Cardiovascular Medical and

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Skin and Stem Cell Research Center

Full name of responsible person

Nooshafarin Kazemikhoo

Position

Medical Genetics PhD

Other areas of specialty/work

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Skin and Stem Cell Research Center

Full name of responsible person

Fereshteh Ansari

Position

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Other areas of specialty/work**Street address**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty