Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 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 Rajaee 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

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Fereshteh Ansari
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Razi Vaccine and Serum Research Institute
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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 Rajaee
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 fibrilation
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 vain 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
Tehran
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
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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