

# Left main coronary artery disease treatment, a comparison of bypass graft and stent treatments in Spain

|  |   |  |
|--|---|--|
| <b>Submission date</b><br>19/10/2019   | <b>Recruitment status</b><br>Stopped            | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>22/10/2019 | <b>Overall study status</b><br>Stopped          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>21/08/2023       | <b>Condition category</b><br>Circulatory System | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

The narrowing of the coronary arteries (also called 'coronary heart disease') causes chest pain (angina), heart attacks, and heart failure.

Left main disease is the blockage of the left main coronary artery. This study aims to compare two treatments: coronary artery bypass grafting (CABG) versus percutaneous coronary intervention (PCI) with the use of a drug-releasing stent.

A coronary artery bypass graft (CABG) is a surgical procedure used to treat coronary heart disease. It diverts blood around narrowed or clogged parts of the major arteries to improve blood flow and oxygen supply to the heart.

A coronary angioplasty (also known as percutaneous coronary intervention) is a procedure used to widen blocked or narrowed coronary arteries (the main blood vessels supplying the heart). Angioplasty means using a balloon to stretch open a narrowed or blocked artery. However, most modern angioplasty procedures also involve inserting a short wire-mesh tube, called a stent, into the artery during the procedure. The stent is left in place permanently to allow blood to flow more freely

### Who can participate?

Patients aged 18 years or over who are due to have coronary artery surgery or percutaneous coronary intervention

### What does the study involve?

Participants will be randomised to receive one of the two treatments described above

### What are the possible benefits and risks of participating?

Patients participating of the trial will be benefited from a close follow up which will last one

year. Since this trial will test standard revascularization procedures, participating patients will not suffer from any additional risk compared with those submitted to revascularization procedure out of the present trial

Where is the study run from?

Hospital Universitario Dr. Negrín, Las Palmas de Gran Canaria, Spain

When is the study starting and how long is it expected to run for?

February 2017 to February 2026

Who is funding the study?

Fundación Canaria de Investigación y Salud (Canary Islands Foundation for Health and Research; Spain) Colegio de Medicos de Las Palmas (Spain)

Who is the main contact?

Dr Stefano Urso

stefano\_urso@inwind.it

## Contact information

### Type(s)

Scientific

### Contact name

Dr Stefano Urso

### ORCID ID

<https://orcid.org/0000-0002-7239-3195>

### Contact details

Hospital Universitario Dr. Negrín

Cirugía Cardíaca, Calle Plaza Barranco de la Ballena

Las Palmas

Spain

35010

+34928450000

stefano\_urso@inwind.it

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

44731574R

## Study information

### Scientific Title

Left Main Spanish COronary REvascularization trial

## **Acronym**

LM-SCORE

## **Study objectives**

Current hypothesis as of 04/11/2020:

The objective of the present study is to determine the difference in terms of MACE events (major adverse cardiovascular events) plus bleeding events between coronary surgery with double arterial graft and percutaneous revascularization with second-generation stent.

Previous hypothesis:

Patients with left main disease treated percutaneously have a significantly higher repeat revascularization events compared to patients who undergo coronary artery bypass grafting with bilateral internal mammary artery.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Current ethics approval as of 17/04/2020:

Approved 31/10/2019, Comité Ético de Investigación Clínica-Comité de Ética en la Investigación con Medicamentos Hospital Universitario de Gran Canaria Dr Negrín (CEI/CEIm HUGCDN) (Calle Plaza Barranco de la Ballena, s/n, 35010 Las Palmas de Gran Canaria, Spain; no telephone number; no email), ref: 2019-400-1

Previous ethics approval:

Approval pending, Ethics Committee of Hospital Universitario Dr. Negrín, Las Palmas De Gran Canaria, Spain.

## **Study design**

National multicenter randomized clinical trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Left main coronary artery stenosis

## **Interventions**

Current hypothesis as of 04/11/2020:

Left Main SCORE trial is a national, multicenter, randomized clinical trial whose objective is to compare two myocardial revascularization strategies in patients with left main disease (LMD): coronary artery bypass grafting (CABG) with the use of bilateral mammary artery or single mammary artery plus radial artery versus percutaneous coronary intervention (PCI) with the use of a second-generation drug-eluting stent (everolimus). The present clinical trial will have a 1-year clinical follow-up and will be open to evaluate an extension of follow-up to 5 years.

Randomization will be carried out by a randomization software in permuted blocks by Hospital with stratification by diabetes (present/absent). Treatment allocation based on random software-generated sequences will be blind to analyzers.

Patients with left main disease will be randomized, according to random software-generated sequences, in two groups: coronary artery bypass grafting (CABG) with the use of bilateral mammary artery (Control) and percutaneous coronary intervention (PCI) with the use of a second-generation drug-eluting stent (Intervention).

---

Previous intervention:

Left Main SCORE trial is a national, multicenter, randomized clinical trial whose objective is to compare two myocardial revascularization strategies in patients with left main disease (LMD): coronary artery bypass grafting (CABG) with the use of bilateral mammary artery versus percutaneous coronary intervention (PCI) with the use of a second-generation drug-eluting stent (everolimus). The present clinical trial will have a 1-year clinical follow-up.

Randomization will be carried out by a randomization software in permuted blocks by Hospital with stratification by diabetes (present/absent). Treatment allocation based on random software-generated sequences will be blind to analyzers.

Patients with left main disease will be randomized, according to random software-generated sequences, in two groups: coronary artery bypass grafting (CABG) with the use of bilateral mammary artery (Control) and percutaneous coronary intervention (PCI) with the use of a second-generation drug-eluting stent (Intervention)

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Current primary outcome measures as of 07/12/2020:

Primary outcomes will be recorded in patient medical records at 1 month, 6 months and 12 months. The present protocol leaves open the possibility to extend the follow-up to 5 years, depending on financial support.

1. Incidence of repeated revascularization
2. Combined incidence of global mortality, stroke, myocardial infarction related to the procedure, myocardial infarction unrelated to the procedure, repeated revascularization ('MACCE' events)

---

Previous primary outcome measures:

1. Incidence of repeated revascularization
2. Composed incidence of global mortality, stroke, myocardial infarction related to the procedure, myocardial infarction unrelated to the procedure, repeated revascularization ('MACCE' events) (time frames of 1 month, 6 months, 12 months).

## **Key secondary outcome(s)**

Current secondary outcome measures as of 07/12/2020:

Secondary outcomes will be recorded in patient medical records at 1 month, 6 months and 12 months. The present protocol leaves open the possibility to extend the follow-up to 5 years,

depending on financial support.

1. Overall mortality
2. Cardiac death
3. Myocardial infarction related to the procedure
4. Myocardial infarction unrelated to the procedure
5. Revascularization of the target lesion
6. Revascularization of the coronary segment other than the target lesion
7. Revascularization of the left main stem (LMS)
8. Stroke
9. Stent thrombosis and symptomatic graft occlusion
10. Angina according to the Canadian Cardiovascular Society (CCS) classification
11. Functional class according to NYHA classification
12. Health cost assessment

---

Previous secondary outcome measures:

Incidence of each of the following individual variables (time frames of 1 month, 6 months, 12 months):

1. Overall mortality
2. Cardiac death
3. Myocardial infarction related to the procedure
4. Myocardial infarction unrelated to the procedure
5. Revascularization of the target lesion
6. Revascularization of the coronary segment other than the target lesion
7. Revascularization of the left main stem (LMS)
8. Stroke
9. Stent thrombosis and symptomatic graft occlusion
10. Angina according to the Canadian Cardiovascular Society (CCS) classification
11. Functional class according to NYHA classification
12. Health cost assessment

### **Completion date**

01/02/2026

### **Reason abandoned (if study stopped)**

Lack of staff/facilities/resources

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 04/12/2020:

1. Aged >18 years
  2. Scheduled for myocardial revascularization and eligible to be treated with CABG or PCI due to left main trunk disease (LMD) or equivalent ± other coronary lesions
  3. SYNTAX score of 22 or less
  4. Able to sign the informed consent
  5. Capable of complying with medical treatment after the procedure
  6. Able to comply with the follow-up for 5 years
-

Previous inclusion criteria:

1. Aged between 18 - 80 years
2. Scheduled for myocardial revascularization and susceptible to being treated with coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI) for left main stem disease (LMSD) or LMS equivalent  $\pm$  additional significant coronary lesions diagnosed by coronary angiography. The LMSD will be defined as  $\geq 50\%$  stenosis documented by angiographic visual estimation or as a fractional flow reserve  $<0.80$ . The LMSD will be represented by the following Medina classification patterns: 1,1,1-1,0,1-1,1,0. The LMS equivalent will be defined by the presence of a disease (classified as 0,1,1) of ostial left anterior descendant artery and ostial circumflex artery producing a  $\geq 70\%$  stenosis by angiographic visual estimation or with a fractional flow reserve  $<0.80$ . Coronary lesions that do not affect the trunk will be considered susceptible to revascularization when they will affect a coronary artery with a diameter  $\geq 1.5$  mm and when they will produce a  $\geq 70\%$  stenosis documented by angiographic visual estimation, or when they will present a reserve of fractional flow  $<0.80$
3. SYNTAX score of 32 or less
4. Possibility of signing the informed consent
5. Capable of complying with post-procedure medical treatment
6. Able to be followed up for a year

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

0

### **Key exclusion criteria**

Current inclusion criteria as of 04/12/2020:

1. SYNTAX score  $>22$
2. Myocardial Infarction with ST elevation of less than 24 h of evolution
3. Cardiogenic shock
4. Requiring emergent myocardial revascularization: less than 6 h from the diagnosis of left main disease until the revascularization procedure
5. Unfavorable anatomy for PCI: additional calcified or severe tortuous coronary lesions
6. The presence of specific characteristics of the coronary lesion or clinical conditions that lead the interventional cardiologist or participating cardiac surgeon to believe that the clinical equipoise between PCI and CABG is not present
7. Need for any concomitant cardiac surgery other than isolated aorto-coronary bypass.
8. Previous cardiac surgery

9. Expected survival <5 years
10. Allergy to aspirin or P2Y12 receptor inhibitors.
11. Allergy to medications associated with the drug eluting stent.
12. Inability to sign informed consent.
13. Patients unable to comply with post-procedure medical treatment.
14. Patients unable to be followed up for at least 1 year

---

Previous exclusion criteria:

1. Body mass index >40 kg/m<sup>2</sup>
2. Myocardial Infarction with ST elevation of less than 24 h of evolution
3. Cardiogenic shock
4. Requiring emergent myocardial revascularization: less than 6 h from the diagnosis of left main disease until the revascularization procedure
5. Unfavorable anatomy for PCI: additional calcified or severe tortuous coronary lesions
6. The presence of specific characteristics of the coronary lesion or clinical conditions that lead the interventional cardiologist or participating cardiac surgeon to believe that the clinical equipoise between PCI and CABG is not present
7. Need for any concomitant cardiac surgery other than isolated aorto-coronary bypass.
8. Previous cardiac surgery
9. Expected survival <1 year
10. Allergy to aspirin or P2Y12 receptor inhibitors.
11. Allergy to medications associated with the drug eluting stent.
12. Inability to sign informed consent.
13. Patients unable to comply with post-procedure medical treatment.
14. Patients unable to be followed up for at least 1 year

**Date of first enrolment**

01/12/2021

**Date of final enrolment**

01/12/2023

## **Locations**

**Countries of recruitment**

Spain

**Study participating centre**

**Hospital Universitario Dr. Negrín**  
Calle Plaza Barranco de la Ballena  
Las Palmas de Gran Canaria  
Spain  
35010

**Study participating centre**

**Hospital Universitario Insular**  
Calle Francisco Hernández González, 1  
Las Palmas  
Spain  
35016

**Study participating centre**  
**Complejo Hospitalario de Navarra**  
Calle de Irunlarrea, 3  
Pamplona  
Spain  
31008

**Study participating centre**  
**Hospital Universitario Germans Trias i Pujol**  
Carretera de Canyet  
Badalona, Barcelona  
Spain  
08916

**Study participating centre**  
**Hospital Virgen de la Salud**  
Av. de Barber, 30  
Toledo  
Spain  
45004

## **Sponsor information**

**Organisation**  
Comité de Ética de Investigación con medicamentos

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**

Fundación Canaria de Investigación y Salud

**Alternative Name(s)**

Canary Islands Foundation for Health and Research, Canary Foundation and Health Research, FUNCIS

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Spain

**Funder Name**

Colegio de Medicos de Las Palmas

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

The current data sharing plans for this study are unknown and will be available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date