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

Submission date 19/10/2019	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/10/2019	**Overall study status** Stopped	
Last Edited 21/08/2023	**Condition category** Circulatory System	

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 no 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

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.

Primary study design
Interventional

Study design
National multicenter randomized clinical trial

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 havea 1-year clinical follow-up and will be open to evaluate a extension of follow-up to 5 years.

Randomization will be carried out by a randomization software in permutated 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).

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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 permutated 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)

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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

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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. cheduled 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

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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 ± additional significant coronary lesions diagnosed by coronary angiography. The LMSD will be defined as ≥ 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 ≥ 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 ≥ 1.5 mm and when they will produce a ≥ 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

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Previous exclusion criteria:
1. Body mass index >40 kg/m2
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