ISRCTN11781836 https://doi.org/10.1186/ISRCTN11781836

Results of coronary artery bypass surgery in diabetic patients

Submission date	Recruitment status	[ ] Prospectively registered
02/07/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/07/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/07/2019	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Coronary artery disease is the term that describes what happens when the heart's blood supply is blocked or interrupted by a build-up of fatty substances in the coronary arteries. Coronary artery bypass grafting (CABG) is also known as bypass surgery, a heart bypass, or coronary artery bypass surgery. Type 2 diabetes is a common condition that causes the level of sugar (glucose) in the blood to become too high.

Aims:

- Define the factors that can predict hospital mortality after coronary bypass surgery in patients with type 2 diabetes.
- Evaluate adverse heart and brain events that occur after surgery.
- Evaluate the risk of readmissions to hospital and the need for surgical or percutaneous myocardial revascularization.
- Calculate medium and long term mortality and identify its predictive factors.

Who can participate?

Patients at Mohammed V teaching military hospital, who have type 2 diabetes mellitus and have undergone a coronary bypass graft to treat coronary artery disease.

What does the study involve?

It concerns only the study of records and collection of data already stored in our local database with no impact on the patient's health and discrimination.

What are the possible benefits and risks of participating?

The study is performed after discharge of patients and does not concern a change of treatment or intervention or anesthesia. Patients participating in the study are not exposed to any risk of side or adverse effects.

Where is the study run from?

Cardiac surgery department - Mohammed V teaching military hospital, Rabat, Morocco.

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

January 2000 to January 2019.

Who is funding the study?
Université Mohammed V de Rabat, Morocco.

Who is the main contact?
Prof. Younes Moutakiallah
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MOR76

Study information

Scientific Title
Comparison of outcome of coronary artery bypass grafting in diabetic and non-diabetic patients: experience of an African center

Study objectives
1. Is diabetes an element of poor prognosis in coronary surgery?
2. Can coronary surgery in diabetics be safely and effectively performed in low-volume centers in

developing countries?
3. What are the predictors of in-hospital morbidity and mortality in diabetic coronary surgery in low-volume centers in developing countries?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending from Comité d'éthique de Recherche Biomédicale (CERB) Faculté de Médecine et de Pharmacie de Rabat Université Mohammed V de Rabat (Rabat, Morocco, 10045; [+212] 0537773560; guedirak@yahoo.fr), ref:

Study design
Single-center retrospective observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Coronary artery bypass in diabetes type 2 patients

Interventions
This is a retrospective study, all patients were already operated on and discharged from the hospital. Data will be collected from the local database and processed without any therapeutic change or intervention.
Data from diabetic patients who underwent coronary artery bypass grafting surgery since 2000 are included. Treatment was according to the usual protocol of the cardiac surgery department and they were followed by our outpatient clinic system.

Intervention Type
Procedure/Surgery

Primary outcome measure
Gathered from patient records from time of operation to end of study:
1. Incidence of postoperative major cardiovascular and cerebral events (MACCE).
2. Incidence of re-hospitalizations, re-interventions and the need for revascularization.
3. The mortality in the medium and long term.

Secondary outcome measures

none

Overall study start date
01/01/2000

Completion date
01/06/2019

Eligibility

Key inclusion criteria
1. Coronary artery disease
2. Diabetes mellitus type 2
3. Coronary artery bypass graft

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
550

Key exclusion criteria
1. Diabetes mellitus type 1

Date of first enrolment
15/01/2019

Date of final enrolment
10/05/2019

Locations

Countries of recruitment
Morocco

Study participating centre
Cardiac surgery department - Mohammed V teaching military hospital
Hay Riyad
Rabat
Morocco
10045

Sponsor information

Organisation
Faculty of medicine and pharmacy of Rabat - Mohammed V university

Sponsor details
Hay Souissi
Rabat
Morocco
10045
+212 537 77 37 01
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Sponsor type
University/education

Website
http://fmp.um5.ac.ma/

ROR
https://ror.org/00r8w8f84

Funder(s)

Funder type
University/education

Funder Name
Université Mohammed V de Rabat

Alternative Name(s)
Mohammed V University, University Mohammed V in Rabat, Mohammed V University in Rabat, Université Mohammed V à Rabat, Mohammed V University of Rabat, UM5

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
France

Results and Publications

Publication and dissemination plan
The study will be submitted for publication in a Biomed Central journal as soon as possible.

Intention to publish date
01/08/2019

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