

Results of coronary artery bypass surgery in diabetic patients

Submission date 02/07/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/07/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/07/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
dryouns@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Younes Moutakiallah

ORCID ID
<https://orcid.org/0000-0001-5600-1246>

Contact details
Service de chirurgie cardiaque - Hôpital militaire d'instruction Mohammed V
Faculté de Médecine et de Pharmacie de Rabat - Université Mohammed V
Rabat
Morocco
10045
+212 537714708
dryouns@hotmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)

Screening

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(s)

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.

Key secondary outcome(s)

none

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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

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