

# Results of coronary artery bypass surgery in diabetic patients

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<b>Registration date</b> 05/07/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/07/2019	<b>Condition category</b> 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  
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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

WebMaster@fmp.um5.ac.ma

## 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