

Incidence of postoperative complications in diabetes or hyperglycaemia

Submission date 22/05/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/06/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/06/2013	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Hyperglycaemia (high blood sugar) may interfere with many biological processes in a recovering surgical patient. In particular in the perioperative phase (at or around the time of operation), some research points towards a strong link on inflammation, renal failure and even cardiac problems in those patients with severely increased glycaemia levels. The aim of the study is to assess in patients undergoing intermediate or high risk surgery the occurrence rate of disturbed glycaemia and to study the effects on outcome variables such as mortality, length of stay in the hospital, infection rate and occurrence of acute kidney injury. These findings will help set up a quality improvement program in our hospital settings.

Who can participate?

All surgical patients who underwent moderate to high-risk surgery in 2011, will be included.

What does the study involve?

Glycaemia preoperatively and on day of surgery, as well as up to 7 days postoperatively will be assessed. Other variables like haemoglobin and creatinine will also be noted in the same way. Also, presence of infection based on clinical symptoms and C-reactive protein (CRP) increase postoperatively (an inflammatory indicator which is also related to occurrence of infection), development of acute renal failure, 30-day mortality, total mortality and finally length of stay in the hospital will be assessed.

What are the possible benefits and risks of participating?

As this is an observational study there is no risk involved.

Where is the study run from?

The study is run from the University Hospital, department of Anesthesiology and Perioperative Medicine in Brussels.

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

The study started in April 2013 and is expected to last till September 2013.

Who is funding the study?
University Hospital Brussels (Belgium) - Department of Anaesthesiology and Perioperative Medicine

Who is the main contact?
Jan Poelaert, MD, PhD
University Hospital Brussels

Contact information

Type(s)
Scientific

Contact name
Prof Jan Poelaert

Contact details
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1090

Additional identifiers

Study information

Scientific Title
Incidence of postoperative complications in diabetes or hyperglycaemia: a retrospective observational study

Study objectives
Assessment of postoperative complications in diabetes or hyperglycaemic patients such as prolonged length of stay in the hospital, infections, renal failure and 30-day mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee UZ Brussel, Approval date: 26/03/2013, ref: 2013/068

Study design
Retrospective observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied

Diabetes Mellitus, Hyperglycaemia, postoperative

Interventions

Variables to be included are glycaemia preoperatively and on day of surgery, postoperative day (POD) 2 and 3, as well as up to 7 days postoperatively (POD 7).

Other variables will also be noted in the same way: haemoglobin, creatinine, and C-reactive protein (CRP). Also, presence of infection, based on clinical symptoms and CRP increase postoperatively, 30-day mortality and total mortality and finally length of stay in the hospital will be assessed.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

30-day mortality

Key secondary outcome(s)

1. Infections
2. Renal failure
3. Length of stay in the hospital

Completion date

01/09/2013

Eligibility**Key inclusion criteria**

All patients (18-85 years) undergoing non-cardiac surgery in 2012
Diabetes patients, hyperglycaemic patients, with normalization of glycaemia after the stress period of the surgery and normoglycaemic patients.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

85 years

Sex

All

Key exclusion criteria

1. Local regional anesthesia
2. Cardiac surgery

Date of first enrolment

01/04/2013

Date of final enrolment

01/09/2013

Locations**Countries of recruitment**

Belgium

Study participating centre

UZ Brussel

Brussels

Belgium

1090

Sponsor information**Organisation**

University Hospital Brussels (Universitair Ziekenhuis Brussel [UZ Brussel]) (Belgium)

ROR

<https://ror.org/038f7y939>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

University Hospital Brussels (Belgium) - Department of Anaesthesiology and Perioperative Medicine

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration