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Incidence of postoperative complications in diabetes or hyperglycaemia

Submission date
22/05/2013

Recruitment status
No longer recruiting

Registration date
14/06/2013

Overall study status
Completed

Last Edited
14/06/2013

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
UZ Brussel
Laarbeeklaan 101
Brussels
Belgium
1090

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No patient information sheet, as this study is retrospective and observational. The ethics committee waived the use of a patient information sheet.

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 measure
30-day mortality

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

Overall study start date
01/04/2013

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
The number is not fixed and depends completely on the surgical activity in that particular investigation year 2011.

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)

Sponsor details
Department of Anaesthesiology and Perioperative Medicine
Laarbeeklaan 101
Brussels
Belgium
1090

Sponsor type
Hospital/treatment centre

Website
http://www.uzbrussel.be

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration