Delirium and blood glucose in older patients undergoing hip surgery

Published: 10-07-2014
Last updated: 20-04-2024

Primary objective:To compare the mean absolute glucose change in postoperative older patients with and without a delirium.Secondary objectives:1. To compare the mean glucose concentration and glucose variability in postoperative older patients with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON41505

Source
ToetsingOnline

Brief title
GLOP- study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Deliria (incl confusion)

Synonym
glucose variability, mean absolute glucose change

Research involving
Human

Sponsors and support

Primary sponsor: Tergooi
Source(s) of monetary or material Support: Tergooi

Intervention

Keyword: delirium, glucose, older patients, variability

Outcome measures

Primary outcome

Mean absolute glucose change per hour (mmol/l/hour)

Secondary outcome

-The mean glucose concentration.

-Glucose variability: standard devation of the mean glucose concentration and coefficient of variation and the mean glucose daily delta change

- The presence of an isolated hypoglycemia or hyperglycemia.

Potential risk factors:

1. Age 2. Gender 3. Body mass index 4. Cigarette smoking 5. Alcohol consumption

6. Introduction of diabetes mellituis treatment

7. Number of glucose influencing drugs. 8. Insulin concentration 9. Occurrence of a delirium. 10.Treatment with antipsychotic drugs. 11. Occurrence of any infection. 12. Nutrition. 13. Vitamin D concentration 14.Pain 15. Iron status

16. Serum triglycerides

17. Blood coagulation

- Length of hospital admission

- 6- months and 1 year mortality

Study description

Background summary

Delirium is frequently observed as a complication after surgery and associated with high morbidity and mortality, especially in older patients. The effect of a delirium on glucose and its variability is not clear. As glycemic variability is suggested to be a risk factor for poor outcome, extending knowledge of glucose metabolism in delirium is necessary.

Study objective

Primary objective:
To compare the mean absolute glucose change in postoperative older patients with and without a delirium.

Secondary objectives:
1. To compare the mean glucose concentration and glucose variability in postoperative older patients with and without a delirium.
2. To compare the incidence of hypo- and hyperglycemia in postoperative older patients with and without a delirium.
3. To identify risk factors for changes in mean absolute glucose change in postoperative older patients with a delirium.
4. To determine the association between the mean absolute glucose change and functional and cognitive function, the length of hospital stay and mortality.

Study design

Monocenter, investigator initiated, observational, prospective cohort study.

Study burden and risks

This observational study has negligible risks and a minimal impact for participating patients. This study has no intervention in patients treatment. Integration of regular blood sampling and blood sampling for study purposes will be attempted were possible. This study will extend our knowledge about glucose metabolism in delirium

Contacts

Public
Tergooi

Van Riebeeckweg 212
Hilversum 1213 XZ
NL
Scientific
Tergooi

Van Riebeeckweg 212
Hilversum 1213 XZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 70 years or older.
Admitted to the Geriatric trauma unit or to the department of Orthopaedics for hip surgery.
An increased risk for the development of delirium using the Tergooi questionaire based on the Safety Management System theme 'vulerable older patients'.
Inclusion within 24 hours after hospital admission.
The patient speaks either Dutch or English.
Patient must be able to give written informed consent.

Exclusion criteria

Patients presenting with a diminished capacity to consent at admission.
Patients with a diagnose of diabetes mellitus and/ or treated with oral antidiabetic drugs or insulin.
Patients who are fed with parenteral nutrition during their hospital stay.
Patients who are enrolled in a study with a medicinal product.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-03-2015
Enrollment:	145
Type:	Actual

Ethics review

Approved WMO

Date:	10-07-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	14-04-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Not approved

Date:	04-12-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL47733.041.14