Which can predict memory problems after surgery better; blood sugar levels or memory before surgery?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26065

Source Nationaal Trial Register

Brief title PIANO study

Health condition

Diabetes; impaired glucose tolerance; frailty; neurocognitive dysfunction; postoperative cognitive dysfunction

Sponsors and support

Primary sponsor: Sponsor: Amsterdam UMC - location AMC, Department of Anesthesiology **Source(s) of monetary or material Support:** N/A

Intervention

Outcome measures

Primary outcome

- Changes in scores for the TICS questionnaire administered preoperative vs. 1 month, 3 and 12 months postoperative

1 - Which can predict memory problems after surgery better; blood sugar levels or me ... 30-05-2025

Secondary outcome

- Correlation of preoperative metabolic impairment and postoperative neurocognitive outcome
- Changes in scores for the WHODAS 2.0 questionnaire administered preoperative vs. 6 months postoperative
- Correlation between the G8 frail scale score preoperative and postoperative neurocognitive outcome
- Correlation between demographics (age & gender) and postoperative neurocognitive outcome
- Correlation between BMI and postoperative neurocognitive outcome
- Correlation between medical history and postoperative neurocognitive outcome
- Correlation between medication use and postoperative neurocognitive outcome

Study description

Background summary

Postoperative cognitive dysfunction (POCD) occurs relatively frequently after surgery. POCD has been shown to increase the risk of subsequent dementia as well as premature death. However, because of poor characterization of the syndrome and resulting lack of diagnostic criteria, substantial variation exists in reported incidence rates.

Evidence is growing that impaired glucose metabolism and diabetes mellitus are associated with POCD, though the pathophysiology remains largely unknown. Possible mechanisms include autonomic neuropathy, hyperglycaemia induced neurotoxic changes, temporary states of hypoglycemia caused by antihyperglycemic treatment and pre-existing vascular damage.

The primary question is whether patients with impaired glucose metabolism or diabetes mellitus who get POCD have preexisting cognitive dysfunction, or if this results from the procedure.

We hypothesize that POCD depends largely on preoperative cognitive dysfunction and frailty, rather than metabolic impairment alone.

Clarifying the potential role of diabetes, glycemic levels and a history of hypoglycemia is important to be able to provide reliable risk assessment prior to surgery, to tailor postsurgery clinical care and to inform hypotheses on the mechanisms leading up to POCD. To answer our research question, we aim to perform a prospective cohort study in patients >65 years old undergoing elective surgery.

Study objective

We hypothesize that POCD depends largely on preoperative cognitive dysfunction and frailty, rather than metabolic impairment alone.

Study design

Preoperative: TICS-M and WHODAS 2.0 questionnaire, G8 frail scale, blood tests (incl. HbA1c, Na, K, creatinine) One month postoperative: TICS-M questionnaire and WHODAS 2.0 questionnaire Six months postoperative: TICS-M questionnaire and WHODAS 2.0 questionnaire

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

All patients \geq 65 years old that visit the preoperative screening at the anesthesia outpatient clinic.

Exclusion criteria

Patients \geq 65 years old who do not wish to participate in cognitive screening.

Study design

3 - Which can predict memory problems after surgery better; blood sugar levels or me ... 30-05-2025

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	20-02-2019
Enrollment:	150
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion	
Date:	19-02-2019
Application type:	First submission

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
NTR-new	NL7530
Other	METC Amsterdam UMC, location AMC : W19_044 # 19.067

Study results