

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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26065

Bron

Nationaal Trial Register

Verkorte titel

PIANO study

Aandoening

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

Ondersteuning

Primaire sponsor: Sponsor: Amsterdam UMC - locatie AMC, Department of Anesthesiology

Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 post-surgery 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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

Amsterdam UMC, location AMC
dr. J. Hermanides

0031-205669111

Wetenschappelijk

Amsterdam UMC, location AMC
dr. J. Hermanides

0031-205669111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	20-02-2019
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies	
Datum:	19-02-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7530
Ander register	METC Amsterdam UMC, location AMC : W19_044 # 19.067

Resultaten