Biomarker Development for Postoperative Cognitive Impairment in the Elderly

Published: 10-12-2014
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The overall objective of this study is to identify valid biomarkers for POD/POCD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Deliria (incl confusion)
Study type	Observational invasive

Summary

ID

NL-OMON44903

Source
ToetsingOnline

Brief title
BioCog

Condition

- Deliria (incl confusion)

Synonym
confusion, memory deficits

Research involving
Human

Sponsors and support

Primary sponsor: Charite Berlijn
Source(s) of monetary or material Support: Europese Unie FP7 HEALTH 2013 INNOVATION 1 aanvraag

Intervention

Keyword: biomarkers, neuroimaging, postoperative cognitive dysfunction, postoperative delirium

Outcome measures

Primary outcome

Primary endpoints: POCD rate at 3 month follow up.

Study determinants that are investigated include patient characteristics,

molecular and genetic biomakers determined from blood sampling, and

neuroimaging biomarkers.

Secondary outcome

Secondary endpoints are: POD rate during hospital admission, POCD rate at day 7

(or at the first testable day thereafter, or at the day of discharge), duration

and severity of POD, and severity of POCD at day 7 and at the 3 month follow

up. Further, we will study functional connectivity in delirium, hallucinations

without delirium, and a state without hallucinations and delirium in a

substudy.

Study description

Background summary

Cognitive impairment is increasingly prevalent in our society as a result of aging and different, interacting medical conditions. An acute model of cognitive impairment is postoperative cognitive dysfunction (POCD) which is characterized by the progressive deterioration of cognitive function following surgery with an incidence up to 20-50% early after the intervention, particularly in elderly patients. An acute phase in cognitive dysfunction, Postoperative Delirium (POD) may be followed by this more chronic POCD phase. The socioeconomic implications of postoperative cognitive impairments are profound: both POD and POCD are associated with longer hospital stay and

associated costs, increased mortality, and dependency on social transfer payments. A better understanding of POD/POCD may serve as an inroad into our understanding of multifactorial cognitive impairment and may facilitate the development of novel treatments.

Study objective

The overall objective of this study is to identify valid biomarkers for POD/POCD.

Study design

Prospective, multicenter, observational cohort study.

Study burden and risks

The burden to participate in this study is moderate and the risks associated with study participation are low. Site visits will involve amongst others neuroimaging and neuropsychological examinations. Furthermore, at several time points blood samples will be drawn. The tests described in this protocol are commonly used in clinical practices and/or research studies. Risks associated with MRI procedures are minimal. An unforeseeable risk related to participation in this study is the possible discovery of claustrophobia when entering the small MRI scanning space which may be unknown to the subject. Subjects will be able to terminate study participation at any time, for any reason. The acquired knowledge from this study will enable the selection and integration of highly sensitive neuroimaging, molecular and genetic biomarkers to guide treating physicians in future patient care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Male and female participants aged 65 years or older,
2. Ability to give informed consent after verbal and written information,
3. European ancestry (up till grandparents) for homogeneity reasons for the molecular and genetic investigations.
Patients also need to meet the following criteria:
4. Undergoing elective surgery,
5. Planned operation time > 60 minutes.

Exclusion criteria

1. MMSE score * 23,
2. Planned intracranial operation,
3. Any medical (e.g., vision or hearing) or (neuro)psychiatric condition that would make neuropsychological and/or neuroimaging testing impossible,
4. Claustrophobia or other reasons (e.g., large tattoos) that make the participant unsuitable to undergo MRI investigations,
5. Homelessness or other circumstances where the patient would not be reachable by phone or postal services during follow-up,
6. Participation in an intervention study during study participation,
7. Admission under judicial or official orders,
8. Life expectancy less than 1 year,
9. Withdrawal of informed consent to store, use and distribute pseudomized data which will be gathered during the clinical study period.
Control participants additionally will be excluded if the following criterion applies:
10. Elective or emergency surgery during the study period.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-01-2015
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	10-12-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-10-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-04-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-10-2016
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-12-2017
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
ClinicalTrials.gov	NCT02265263
CCMO	NL50245.041.14