The HCBx permanent AF substudy: The contribution of AF related hemodynamics to structural brain abnormalities and cognitive function decline

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON54040

Source
ToetsingOnline

Brief title
The HBCx Permanent AF substudy - MIND AF

Condition

- Cardiac arrhythmias
- Structural brain disorders
- Cognitive and attention disorders and disturbances

Synonym
a-fib, atrial fibrillation, cognitive impairment, memory disorder

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: CVON/Hartstichting

Intervention

Keyword: Cognitive functioning, Hemodynamics, MRI Brain lesions, Permanent atrial fibrillation

Outcome measures

Primary outcome

Cognitive functioning at baseline and cognitive decline at two year follow up

measured with neuropsychological assessment.

Secondary outcome

Heart rate variability and irregularity

Peripheral blood pressure variation

Structural brain abnormalities

Risk factors

Study description

Background summary

Atrial fibrillation is a growing public health problem, reaching epidemic proportions. There is also growing evidence that AF is independently associated with cognitive impairment and dementia. Mechanisms are still largely unknown, but hemodynamic instability and effects on cerebral perfusion have been reported. It is important to clarify the hemodynamic and vascular contribution of AF to vascular cognitive impairment (VCI) and increase the awareness of cardiologists for the heart brain connection. This study will be part of the Heart-Brain connection Crossroads (HCBx) project. One of the aims of this project is to further unravel the roll of hemodynamic instability and the development of VCI.
More research is necessary to more precisely establish the relation between hemodynamic abnormalities in permanent atrial fibrillation, possibly mediated

through altered brain structure and perfusion, and vascular cognitive impairment.

Study objective

We aim to assess the association between variability and irregularity in heart rate (as caused by permanent atrial fibrillation), and cognitive function.

In addition, variability and irregularity of the peripheral blood pressure will be correlated to heart rhythm, as well as cognitive function. To correlate anatomical changes (e.g. emboli, brain laesions) to cognitive decline, a brain MRI is performed.

Study design

Prospective observational cohort study with a follow up period of two years. All subjects will undergo the same standardized set of clinical, neuropsychiatric and imaging tests to assess cardiovascular risk factors and disease, structural and functional brain and cardiac status, cognitive dysfunction, daily functioning and presence of neuropsychiatric symptoms. After two years assessment of daily functioning and neuropsychiatric symptoms include cognitive function and brain MRI will be repeated.

Study burden and risks

All research data are collected through standard medical procedures and no experimental intervention is performed. The additional risk of this study is considered negligible. The burden of participation consists of time investment at both baseline and follow up (120 minutes for clinical assessment and neuropsychological testing, a maximum of 30 minutes for MRI scanning). However, this study will contribute to knowledge of hemodynamic factors associated with cognitive decline which form possible targets for future therapy.

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

Age 60-80 years (stratified in 60-65, 66-70, 71-75, 76-80 years, minimal 20 patients per group)
Knowledge of Dutch language
Permanent AF
Able to undergo MRI
Able to undergo cognitive testing
Mandatory use of coagulation
Gender stratification 50/50 (bandwidth 40%-60%)

Exclusion criteria

A clinical diagnosis of dementia is a contra-indication for participation in this study
Other neurological or psychiatric diagnosis that affects cognitive performance or testing, such as severe traumatic brain injury or substance abuse
A history of stroke
A pacemaker/ICD in situ >5% ventricular pacing
Severly impaired LVEF
PVI or CABG in the past three months

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-02-2022
Enrollment:	103
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-12-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL76057.029.21