Structural brain damage and cognitive impairment as causes of decreased educational level and employment among adults with congenital heart disease.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac and vascular disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON37011

Source
ToetsingOnline

Brief title
COCO: COgnition in COngenital heart disease

Condition

- Cardiac and vascular disorders congenital
- Structural brain disorders

Synonym
adult congenital heart disease, brain damage

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ICIN (onderdeel KNAW)

Intervention

Keyword: brain damage, congenital heart disease, education, employment

Outcome measures

Primary outcome

Main endpoints are findings from radiological (MRI) and neuropsychological

examination.

Secondary outcome

Educational levels, (un)employment, presence of work related problems, scores

from the WAI-1 question.

Study description

Background summary

Rationale: Patients with congenital heart disease (CHD) are at increased risk for neurological damage through many pathophysiological ways, especially those with cyanotic defects. Even mild but especially more severe defects, are also associated with more unemployment and lower educational levels. We wonder whether this is due to cognitive impairment and if so, if this is due to structural brain damage or social factors. Little about this in adults is known.

Study objective

The primary objective is to evaluate the presence of brain damage (defined by white matter lesions (WMLs) or cerebral atrophy or deviations at neuropsychological examination (NPE)) among adults with tetralogy of Fallot (TOF). The secondary objective is to relate these findings to educational levels and the presence or absence from unemployment or work related problems.

Study design

This study has a singlecentre, prospective observational cohort study design.

Study burden and risks

No new interventions are involved in this study. Participants will undergo a planned cardiac MRI scan to which a MRI of the brain will be added. There is no need for the administration of contrast agents. Radiation exposure is not applicable. Additionally a short questionnaire, abbreviated NPE and laboratory test will take place.

The study has a low but potential risk of an unexpected finding on the MRI-scan of the brain and of experiencing the NPE as burdensome. The additional burden for the patients mainly consists of the time needed for the investigations, which is estimated at an additional three hours.

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

- adult age
- known with tetralogy of Fallot (TOF)
- being willing and able to participate (informed consent)

Exclusion criteria

- any mental retardation syndrome that is evidently caused by another cause than the CHD (for example a chromosomal disorder)
- contra-indications for MRI (claustrophobia, inability to lie flat during a minimum of 30 minutes, presence of any magnetisable metal in the body)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	20-12-2012
Application type:	First submission

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	NL41568.018.12