The relationship between depressive symptoms and pro-inflammatory cytokine serum levels in adults with congenital heart disease

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The current pilot-study will examine the relation between depressive symptoms and serum levels of pro-inflammatory cytokines in CHD-patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Congenital cardiac disorders
Study type	Observational invasive

Summary

ID

NL-OMON35960

Source
ToetsingOnline

Brief title
Depression and cytokine serum levels

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym
Congenital heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Interuniversitary Cardiology Institute of the Netherlands

Intervention

Keyword: - congenital heart disease, - depressive symptoms, - pro-inflammatory cytokine serum levels

Outcome measures

Primary outcome

The association between depressive symptoms and the serum levels of the

pro-inflammatory cytokine TNF-* in adult CHD-patients.

Secondary outcome

The association between depressive symptoms and the serum levels of the

pro-inflammatory cytokines IL-1 and IL-6 in adult CHD-patients.

Study description

Background summary

Morbidity among patients with a congenital heart disease (CHD) is substantial: more than 60% of the patients have undergone one or more cardiac operations, 32% of the patients have had one or more complications, such as endocarditis, stroke, hypertension, or heart failure (HF). Moreover, HF is identified as the number one risk factor of death in CHD-patients. Besides the above traditional co-morbidities, preliminary results of the EXACD-study (an ongoing study investigating the EXperiences of Adults with a Congenital heart Defect) show that the prevalence of depressive symptoms in CHD-patients is more than three times higher than that in the general population. Extensive research has shown that depression is a risk factor for the development and progression of cardiovascular diseases (CVD*s), including HF. Preliminary results of the EXACD-study are in line with this conclusion, showing a Spearman rank correlation of .35 between depressive symptoms and the degree of HF (NYHA-class). Researchers have suggested an immunological mechanism underlying the negative effects of depression in patients with HF or other CVD*s. Two lines of research support this suggestion: 1) the causative role of pro-inflammatory cytokines, in particular Tumor Necroses Factor-alpha (TNF-*), interleukin (IL-)1 and IL-6, in the pathogenesis of HF has been extensively

documented, and 2) both experimental and clinical studies in various patient groups have described a relation between depressive symptoms and increased serum levels of these three pro-inflammatory cytokines. Thus far, however, the relation between depressive symptoms and pro-inflammatory cytokine serum levels has never been studied in CHD-patients. There is reason to believe that the relation between the level of depressive symptoms and pro-inflammatory cytokines does not automatically apply to CHD-patients. That is, CHD-patients show an adaptive response, namely the upregulation of cytokines. CHD-patients show deviant cytokine levels at early age, which remains during adulthood. In contrast, patients with acquired hearth diseases develop deviant cytokine levels as their disease develops. Examining the relation between depressive symptoms and cytokine levels in CHD-patients is therefore needed. Confirmation of this relation in this group of patients is a first step in understanding the associations between depressive symptoms, pro-inflammatory cytokines and HF in CHD-patients. Subsequently, future longitudinal studies can then be developed to investigate the possibility of a causal relation between elevated pro-inflammatory cytokine serum levels accompanying depressive symptoms and the development/ progression of HF in CHD-patients. Ultimately, these results may provide useful information for the development of new treatment options for both depressive symptoms and HF in CHD-patients. Anti-depressants, with their anti-inflammatory effects might be an option, not only treating the depressive symptoms, but perhaps also reducing the risk to develop or progress HF.

Study objective

The current pilot-study will examine the relation between depressive symptoms and serum levels of pro-inflammatory cytokines in CHD-patients.

Study design

We will adopt a cross-sectional design.

Study burden and risks

Filling out a questionnaire assessing the level of depressive symptoms is non-invasive and free of risk (completion takes approximately 10 minutes). The burden for both CHD-patients is the blood sample (10 minutes) in order to assess pro-inflammatory cytokine serum levels.

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

Patients
- are 18 years or older
- have a congenital heart defect (excluding patients with a syndrome, such as Marfan or Noonan)
- are visiting the outpatient cardiology clinic of the AMC

Exclusion criteria

Patients are not eligible if one or more of the following criteria apply:
- they are diagnosed with a syndrome (such as Marfan or Noonan)
- they are mentally impaired
- they are unable to independently complete a questionnaire
- they are not literate in Dutch

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2011
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO

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	NL35908.018.11