HIF and EPO receptor signaling In Heart Failure

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON34760

Source
ToetsingOnline

Brief title
HIF and EPO receptor signaling In Heart Failure

Condition

- Heart failures

Synonym
heart disfunction, Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Erythropoietin, Heart failure, HIF

Outcome measures

Primary outcome

Primary endpoint is myocardial HIF signaling between patients with preserved

versus compromised left ventricular systolic function.

Secondary outcome

Secondary endpoint is the beta common receptor between patients with preserved

versus compromised left ventricular systolic function.

Study description

Background summary

Erythropoietin therapy in heart failure shows promising effects, but possesses undesirable side effects as well, trough elevated haemoglobin levels. The effects of erythropoietin are mediated largely under hypoxic conditions. Earlier research showed the HIF pathway might be of significance in the pathofysiology in heart failure patients. Therefore this pathway needs to be further explored.

Study objective

The primary objective of this study is to asses whether HIF signaling pathways show less activity in patients with preserved ejection fraction compared to patients with systolic dysfunction. Secondary objectives are to assess the relation between cardiac hypertrophy and HIF signaling as well as the relation between HIF and EPO signaling in chronic heart failure. Another objective is to assess the relation between heart failure patients with preserved and ejection fraction and systolic dysfunction and beta common subunit receptor.

Study design

Observational study

Study burden and risks

This study poses a limiting additional risk for the participating patients. The collection of myocardial tissue trough biopsy is performed regularly. It is invasive and provides the risk of perforation and bleeding.

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

Before any study-specific procedure, including assessments for screening, the appropriate written informed consent must be obtained
Man or woman 18 to 80 years of age
Undergoing a planned, elective aortic valve replacement for the first time for aortic stenosis.

Hemoglobin (Hb) concentration * 7.4 mmol/l and * 9.9 mmol/l within 7 days prior to surgery and no major acute blood loss since this Hb determination.

Exclusion criteria

An unstable medical condition, defined as having been hospitalized for a non-cardiac condition within 4 weeks of screening, major surgery within 24 weeks of screening, or otherwise unstable in the judgment of the investigator (e.g., at risk of complications or adverse events unrelated to study participation).
Clinical history of chronic kidney disease (CKD) (at any point prior to registration) defined as serum creatinine > 105 µmol/l for all females, > 130 µmol/l for black males, and > 115 µmol/l for non-black males.
Clinically significant abnormality in chemistry, hematology, or urinalysis parameters performed within the screening period.
Use of any erythropoietic protein (e.g., rHuEPO; Procrit®, Eprex®, Neorecormon®, Epogen®, Aranesp®) within 12 weeks of enrolment.
Positive pregnancy test or known to be pregnant at the time of screening.
Recent (within 3 months) history of alcohol or illicit drug abuse disorder, based on self-report.
Participation in any investigational device or drug trial(s) or receiving other investigational agent(s) within 30 days.
Known positive for HIV antibodies, hepatitis B surface antigen, or hepatitis C antibodies.
Any condition (e.g., unsuitable anatomy of the atrium; psychiatric illness; etc.) or situation that, in the investigator*s opinion, could put the subject at significant risk, confound the study results, or interfere significantly with the subject*s participation in the study.

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):	01-05-2011
Enrollment:	40

Type:	Actual

Ethics review

Approved WMO Date:	06-04-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL31586.042.10