Impact of heart failure on ischaemic preconditioning in humans

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To examine the impact of heart failure on the change in endothelial function in response to ischaemia reperfusion injury. A secondary objective is to explore the ability of ischaemic preconditioning to protect against the decrease in endothelial...

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

Summary

ID

NL-OMON37367

Source
ToetsingOnline

Brief title
IPC-HF

Condition

- Heart failures

Synonym
heart failure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: endothelial function, heart failure, ischemia reperfusion injury, ischemic preconditioning

Outcome measures

Primary outcome

Change in endothelial function after reperfusion injury

Secondary outcome

not applicable

Study description

Background summary

Stenotic lesions ultimately can cause ischemic events. Reperfusion therapy (either pharmacologic, endovascular or surgical) is mandatory for salvage of ischemic tissue. However, during reperfusion several deleterious events take place causing further damage, commonly referred to as ischaemia reperfusion(IR)-injury. A detrimental feature of IR-injury is endothelial damage. A recent study found that advanced age is associated with a larger decrease in endothelial function compared to young subjects, possibly through the presence of an a priori lower endothelial function. Also heart failure is associated with the presence of significant endothelial dysfunction. However, no previous study examined whether heart failure is associated with a larger decrease in endothelial function.
Ischaemic preconditioning (IPC) refers to the reduction of IR-injury induced by brief (repeated) preceding periods of ischemia. Also the arterial endothelium can be protected by IPC. Several studies performed in animals and humans have demonstrated that the protective effects of IPC are attenuated with aging. However, no previous study in humans examined whether the protective effects of IPC on the endothelial function are preserved in heart failure.

Study objective

To examine the impact of heart failure on the change in endothelial function in response to ischaemia reperfusion injury. A secondary objective is to explore the ability of ischaemic preconditioning to protect against the decrease in endothelial function in heart failure.

Study design

cross-sectional observation

Intervention

n/a

Study burden and risks

Non-invasive cuff occlusion is used to examine endothelial function (5-minute ischaemia), apply ischaemic preconditioning (3 cycles of 5-minute ischaemia) and produce the stimulus that induces ischaemia-reperfusion injury (20-minute ischaemia). This repeated cuff inflation is non-invasive and not associated with a health risk f or the subject. The volunteers will not benefit directly from participating in this study.

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

- Heart failure patients (NYHA-classification category II or III + ejection fraction of <=40%)
- Healthy older volunteers (age- and sex-matched)

Exclusion criteria

- Smokers
- Type I or II diabetes mellitus
- Mild renal impairment or proteinuria
- Hepatic impairment
- Hypercholesterolaemia (>=6.5 mmol/L)
- Hypertension
- Atrial fibrillation
- Pre-menopausal females or those on hormone replacement therapy
- Other (serious) pathology, such as chronic obstructive pulmonary disease

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-05-2012
Enrollment:	46
Type:	Actual

Ethics review

Approved WMO Date:	18-04-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL38906.091.11

Study results

Date completed:	01-12-2013
Actual enrolment:	30