Circadian rhythms in heart failure

Published: 05-11-2014
Last updated: 21-04-2024

To investigate whether circadian rhythms in patients with chronic systolic heart failure are disturbed

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

Summary

ID

NL-OMON44589

Source
ToetsingOnline

Brief title
Circadian rhythms in heart failure

Condition

- Heart failures

Synonym
chronic systolic heart failure, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: circadian, failure, heart, rhythm

Outcome measures

Primary outcome

Circadian expression profile of clock (controlled) genes in the blood, e.g.

BMAL 1 (Brain and muscle aryl hydrocarbon receptor nuclear trans locator

(ARNT~}like protein -1, CRY1 (Cryptochrome protein 1), PER2 (Period circadian

protein homolog 2), PER3 (Period circadian protein homolog 3), REV-ERBa, DBP

(Albumin D-box binding protein).

Secondary outcome

Daytime sleepiness (Epworth Sleepiness Scale)

Chronotype (Chronotype questionnaire)

Medication (Medication record)

Food + coffee intake

24h blood pressure profile

24h activity profile (actometer)

24h cardiac electrical activity (ECG) profile

Study description

Background summary

Heart failure is one of the major chronic cardiovascular diseases. It is associated with severely reduced quality of life and a poor prognosis. Interestingly, neurohormones particularly relevant in heart failure, such as glucocorticoids, catecholamines, growth hormone, atrial natriuretic factor, angiotensin II, aldosterone, and renin, exhibit diurnal variation. While it has been long known from clinical practice that patients with heart failure often suffer from insomnia, reversely insomnia was also found to increase the risk of incident heart failure in a prospective study. Strong links have been established between circadian rhythms and renal function (often disturbed in heart failure and vice versa), hypertension (a major contributor to heart

failure), and ischemia*reperfusion tolerance (as in myocardial infarction, also a major contributor to heart failure) both in humans and in mice.

Study objective

To investigate whether circadian rhythms in patients with chronic systolic heart failure are disturbed

Study design

Observational case-control study.

Study burden and risks

Hospitalized chronic systolic heart failure patients and control patients are asked to participate in the following:
- Complete 2 short questionnaires about speepiness and sleeping behaviour
- Keep a diary of food- and fluidintake during 24 hours.
- Blood samples taken at 7 different timepoints (9:00, 13:00, 17:00, 21:00, 1:00, 5:00, and 9:00 hour)
a. PAX gene tubes to stabilize intracellular RNA in blood (2,5ml per timepoint)
b. 7 serum tubes (5ml per timepoint)
- 1 day ambulatory blood pressure measurement (after dismissal, no lifestyle rules)
- 1 day ambulatory Holter monitor (after dismissal, no lifestyle rules)
- 4 days actometer (after dismissal, no lifestyle rules)

The risk and burden of the patients are minimal: all procedures are done during an already planned admission to the hospital and around already planned visits to the outpatient clinic, so patients don't have to come to the hospital especially for the study. In addition, the burden of the measurements is low. The questionnaires are short, there is an easy food- and fluids diary which has to be filled in for only 24 hours, blood will be collected from an existing hypodermic needle and the blood pressure monitor, Holter monitor, and actometer will impede patients minimally in their activities.

There is no direct personal benefit for the participants in this study. The collected data help to understand the circadian clock problems in heart failure patients. In the future this can possibly be used to define therapeutic targets or develop chronopharmacotherapy

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: Patients (18-85 years) with chronic systolic heart failure NYHA II-III that have been admitted to the UMC Utrecht;Controls: Patients (18-85 years) that have been admitted to the hospital

Exclusion criteria

Patients:
-Blindness
-End stage renal failure (GFR < 15ml/min)
-Fever >38C
-CRP >20mg/L
-Use of hypnotics or other medication that disturbs the normal sleep pattern during study period
-Anaesthesia within 48 hours prior to start study
-Serious comorbidity that prevents participation according to the investigators (e.g. severe

neurological, psychiatric, or oncologic diseases);Controls:
- Blindness
- Fever >38C
- CRP >20mg/L
- Use of hypnotics or other medication that disturbs the normal sleep pattern during study period
- Anesthesia within 48 hours prior to start study
- Serious comorbidity that prevents participation according to the investigators (including heart and kidney failure)

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):	05-08-2015
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO Date:	05-11-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-07-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	27-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL50383.041.14