Sulodexide for chronic heart failure: a proof of concept, randomized, open-label, placebo-controlled study

Published: 23-06-2020
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To assess the efficacy of treatment with sulodexide for chronic heart failure.

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

Summary

ID

NL-OMON49874

Source
ToetsingOnline

Brief title
Sulodexide for chronic heart failure

Condition

- Heart failures

Synonym
heart failure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: glycosaminoglycans, heart failure, non-osmotic sodium storage, sulodexide

Outcome measures

Primary outcome

Percent change of NT-proBNP from baseline to week 8.

Secondary outcome

- Blood pressure

- Hemodynamic parameters

- Fluid status

- Monocyte subsets

- Monocyte surface proteins

- Dyspnea symptoms, physical limitations and quality of life

- Distance covered during six minute walking test

- WHO grade II-IV bleeding events

- Incidence of (serious) adverse events

Study description

Background summary

Heart failure is characterized by sodium and water overload despite lifestyle advices and drug therapy. The endothelial surface layer (ESL) is able to neutralize the negative effects of sodium excess such as water retention and high blood pressure. The ESL is damaged in subjects with heart failure. Restoration of the ESL with sulodexide, an oral drug consisting of ESL constituent, may therefore lower sodium and water excess in heart failure patients.

Study objective

To assess the efficacy of treatment with sulodexide for chronic heart failure.

Study design

Proof-of-principle randomized, placebo-controlled trial.

Intervention

Sulodexide 100 mg once daily for 8 weeks or placebo.

Study burden and risks

Subjects need to take study medication every day for 8 weeks. A 24-hour blood pressure measurement will be performed 3 times and 24-hour urine will be collected 3 times. For safety reasons , blood will be sampled 4 times with a total volume of 36 mL. All subjects will be asked to fill in questionnaires 3 times. We will perform several non-invasive measurements such as office blood pressure measurements, microcirculation and hemodynamic Nexfin measurements. 10 patients will be approached for two optional skin biopsies at baseline and after 8 weeks.

Treatment with sulodexide 100 mg has proven to be a safe treatment in >7,000 subjects with a follow-up duration up to 1 year. The incidence of adverse events was comparable to placebo. More than half of these patients had important cardiovascular co-morbidities and were within 2 weeks after acute myocardial infarction.

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

- Chronic heart failure with reduced ejection fraction (HFrEF)
- Elevated NT-proBNP and signs of congestion (e.g. use of diuretics, peripheral edema)
- Stable diuretic and antihypertensive treatment

Exclusion criteria

- Estimated glomerular filtration rate (eGFR) <15 ml/min/1.73m2
- Hypotension (systolic < 105 mmHg or diastolic < 60 mmHg)
- Anticoagulant therapy or double antiplatelet therapy
- Recent cardiovascular event or hospital admission for heart failure

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2020
Enrollment:	64
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Vessel Due F
Generic name:	sulodexide

Ethics review

Approved WMO Date:	23-06-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-07-2020
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
EudraCT	EUCTR2020-002864-30-NL
CCMO	NL73019.018.20