Systolic phases with laminar and turbulent flow in peripheral arteries of patients with congenital valvular aortic stenosis

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON19990

Source
NTR

Brief title
Turbulence in Aorta Stenosis

Health condition

aorta stenosis

Sponsors and support

Primary sponsor: Martini Ziekenhuis Groningen
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Laminar versus turbulent flow within the systolic flow velocity signal measured in arteries at

different locations of the body

Secondary outcome

Timing of stroke onset and transition from laminar to turbulent signal or vice versa. Speed of propagation of stroke onset across the arterial system

Study description

Background summary

Rationale: Blood flow passing a severe stenosis of the aortic valve becomes turbulent. This study aims to follow this turbulence along the arterial system studying the flow velocity at a high temporal resolution and investigating whether turbulence persists during the full duration of systole or whether parts of systole may show laminar flow.
Objective: to test whether turbulence persists during the whole or only during part of systole. Thereby this investigation tests the validity of the so-called theory of arterial acceleration which proposes that the first part of systole originates from a short-lasting stiffening of the muscular layers in the arterial tree and that the second part is due to the actual ejection of blood volume by the heart into the aorta.
Study design: observational follow up study
Study population: patients are recruited from the outpatient clinic of the UMCG cardiology department who are known to have no, moderate or severe aortic stenosis and are aged from 18 - 50 yrs. Each group will consist of 5 patients. Patients with atrial fibrillation are not eligible.
Intervention (if applicable): n.a.
Main study parameters/endpoints: main study parameter is presence of turbulence within the systolic phase of a blood flow velocity measurement and if so, during what part of systole
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: subjects undergo two exams with approximately 3 months interval during which blood flow velocity signals are documented at different locations by duplex ultrasound investigation. The exams are non-invasive and without risk. The data collection is for scientific reasons only.

Study objective

The aim of the present study is: can a single case observation of two distinct phases during systole (laminar and turbulent) be confirmed in other patients with aorta stenosis?

Study design

end of study only

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

Patients are eligible when aged between 18 and 50 years. A total of 10 patients with congenital aortic stenosis are measured and 5 patients with bicuspid valve but without relevant aortic stenosis. The group of patients with congenital aortic stenosis consists of 5 patients with moderate aorta stenosis (v max between 3 to 4 m/s) and 5 patients with a severe aortic stenosis (v max >4 m/s).

Exclusion criteria

atrial fibrillation

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-10-2021
Enrollment:	15
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
PDF file with all patient measurements under randomized code will be presented online as well as the file containing the coding key.

Ethics review

Positive opinion

Date:	04-10-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 51209
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9763
CCMO	NL77569.042.21
OMON	NL-OMON51209

Study results

Summary results
planned only