

Vascular function in patients with chronic vessel inflammation

Submission date 05/01/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 09/01/2016	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 07/01/2016	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Chronic periaortitis is a rare disease of unknown cause that leads to inflammatory tissue around the body's main artery, the aorta. It is known that increased arterial stiffness is associated with an increased risk of heart disease and death. We aim to study arterial stiffness in patients with chronic periaortitis.

Who can participate?

Patients with chronic periaortitis, patients with high blood pressure, and 16 healthy volunteers, matched for sex and age (age range: 34 to 74).

What does the study involve?

Participants have their arterial stiffness measured with two methods: pulse wave velocity (a probe placed over the neck artery and the main leg artery) and digital volume pulse (a probe placed on the index finger). We study the change of digital volume pulse before and after giving the patients the drug nitroglycerin sublingually (under the tongue).

What are the possible benefits and risks of participating?

Benefits include knowing whether you have a marker of heart disease risk and contributing to knowledge about a very rare disease. Sublingual nitroglycerin can sometimes cause a headache, sickness and dizziness. These side effects usually last less than 10 minutes and are not dangerous.

Where is the study run from?

University Hospital of Bern (Switzerland).

When is the study starting and how long is it expected to run for?

January to May 2008.

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Claudia Scheuter

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

1491

Study information

Scientific Title

Arterial stiffness and vascular function in patients with chronic periaortitis – a case-control study

Study objectives

Patients with periaortitis show an elevated arterial stiffness and a reduced vascular function

Ethics approval required

Old ethics approval format

Ethics approval(s)

Kantonale Ethikkommission Bern (Ethics Committee of the State of Bern, Switzerland), 07/04/2008, ref: 025/08

Primary study design

Observational

Study design

Observational cross-sectional case-control Study

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Chronic periaortitis, also known as Ormond's disease or retroperitoneal fibrosis is a rare disease of unknown etiology with pathological features of vascular inflammation and fibrosis.

Interventions

We compared arterial stiffness and endothelial function in 16 patients with chronic periaortitis to age- and sex-matched hypertensive and healthy controls in a 1:1 distribution. Aortic stiffness was assessed by carotid-to-femoral pulse wave velocity with Doppler measurements. Endothelium-independent vasodilation was assessed before and after sublingual administration of glyceryl trinitrate by analyzing changes in arterial stiffness using digital volume pulse (DVP) and the DVP derived stiffness index (SIDVP).

Intervention Type

Device

Primary outcome(s)

Arterial stiffness, measured by pulse wave velocity (PWV). PWV was recorded in a single session, using a Pulse Trace PWV© (Micro Medical Ltd, Rochester, Kent, UK) with a 4-MHz continuous wave directional Doppler pencil probe. Pulse Trace PWV© calculates the time lag between the R wave of the electrocardiogram and the arrival of the arterial pulse wave at 2 different sites, thus inferring pulse wave velocity. First, electrodes for an electrocardiogram are placed, followed by placing the Doppler probe over (1) the right carotid artery and (2) the right or left femoral artery. The position of the Doppler probe is optimized at each site to achieve a signal of sufficient quality (i.e. stable pulse waveform). About 10 systolic peaks are recorded at both sites to obtain a mean time lag at the carotid artery and at the femoral artery. The distance between the 2 detection sites is measured.

Key secondary outcome(s)

Digital volume pulse (DVP) as a measure for endothelial function, blood pressure, heart rate and pulse pressure. DVP was measured photoplethysmographically in the same single session as PWV, using the Pulse Trace© Pulse Contour Analysis device (Micro Medical Ltd, Rochester, Kent, UK). The probe were placed on the index finger of the dominant hand. Pulse contour waves recorded over a period of 10 seconds were averaged by the device to a single waveform. Blood pressure was measured while participants were recumbent for at least 10 minutes.

Completion date

30/05/2008

Eligibility

Key inclusion criteria

Patients: patients with a diagnosis of chronic periaortitis that were followed at our outpatient clinic for Nephrology and Hypertension and patients with known arterial hypertension that were followed at our outpatient clinic for Nephrology and Hypertension, matched for age and sex in a 1:1 fashion.

Healthy volunteers: healthy volunteers from the community and clinic staff, matched 1:1 for age and sex.

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Patients with atrial fibrillation and other cardiac arrhythmias that interfered with study measurements

Date of first enrolment

07/04/2008

Date of final enrolment

30/05/2008

Locations**Countries of recruitment**

Switzerland

Study participating centre

Inselspital University Hospital Bern

Department of Nephrology and Hypertension

Bern

Switzerland

3010

Sponsor information**Organisation**

Inselspital University Hospital Bern (Switzerland)

ROR

<https://ror.org/01q9sj412>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository