ISRCTN92088047 https://doi.org/10.1186/ISRCTN92088047

Vascular function in patients with chronic vessel inflammation

Submission date	Recruitment status	[ ] Prospectively registered
05/01/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/01/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/01/2016	Circulatory System	[ ] 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
Dr Claudia Scheuter

ORCID ID
http://orcid.org/0000-0001-7088-3652

Contact details
Department of Nephrology and Hypertension
Inselspital University Hospital
Bern
Switzerland
3010

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design

Observational cross-sectional case-control Study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
31/01/2008

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

Age group
Adult

Sex
Both

Target number of participants
45 - 50

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)

Sponsor details
Department of Nephrology and Hypertension
Bern
Switzerland
3010

Sponsor type
Hospital/treatment centre

Website
http://www.nephrologie.insel.ch/

ROR
https://ror.org/01q9sj412

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
We plan to publish the results in an open-access medical journal.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository