Mechanistische studie; Glycocalyx measurements in premature atherosclerosis.

Gepubliceerd: 20-09-2007 Laatst bijgewerkt: 18-08-2022

Glycocalyx volume is diminished in subjects with premature atherosclerosis.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29486

Bron
NTR

Verkorte titel
N/A

Aandoening

1. Glycocalyx;

2. Cardiovascular disease;

3. Atherosclerosis;

4. Premature atherosclerosis.

Ondersteuning

Primaire sponsor: Academisch Ziekenhuis Maastricht
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Overige ondersteuning: Nederlandse Hartstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The systemic volume of the intravascular glycocalyx in subjects with premature atherosclerosis versus healthy control subjects.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

The pathophysiology of premature atherosclerosis is poorly understood. Patients often display few risk factors, but the clinical manifestations are evident. If atherosclerosis is expressed at a very young age, it is likely that besides the classical risk factors there are also genetic factors that play an important role. Therefore, early detection of vascular changes would make it possible to identify unaffected subjects at risk for atherosclerosis. One of these early vascular alterations might be the changes of the vascular glycocalyx, which is a new component of the vasculature and as been associated with surrogate endpoints of cardiovascular disease.

We therefore, hypothesize that glycocalyx volume is diminished in subjects with premature atherosclerosis.

Objective:

The objective is to measure glycocalyx volume in patients with premature atherosclerosis before the age of 40 years and a positive family history for cardiovascular disease and to compare this with an age and sex matched healthy control group.

Study design:

The study will be an observational case control study.

Study population:

We will select 20 patients with premature atherosclerosis and a positive family history for cardiovascular disease and 20 age- and sex matched healthy control subjects.

Main study parameters/endpoints:

The systemic volume of the intravascular glycocalyx in subjects with premature atherosclerosis versus healthy control subjects.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The nature of the burden consists of a 12 hour fasting period previous to a 2,5 hours visit to our out-patient clinic in which subjects will be subjected to infusion with Dextran 40 and labelled red blood cells, while a number of blood samples will be drawn over time. The incidence of a serious allergic reaction, a risk associated with the infusion of Dextran 40 is 1: 2.000. After injection of a safety bolus with Dextran 1, the incidence of a serious allergic reaction is reduced to 1: 70.000. Several previous studies conducted with some of the same researchers as in AMC (Amsterdam) showed no allergic reactions what so ever.
On the other hand, the benefit of this investigation lies in the fact that this method provides us a systemic technique, which detects early atherosclerotic vascular changes. If our expectations are confirmed, this might renders us with a tool to be able to identify unaffected subjects at risk for cardiovascular disease. By identifying such subjects in an early phase, they might be treated and followed, to prevent atherosclerotic disease. Furthermore, through this study we will be able to learn more about possible mechanisms related to atherosclerotic disease.

Doel van het onderzoek

Glycocalyx volume is diminished in subjects with premature atherosclerosis.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Glycocalyx measurements.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Cases:

Subjects should have premature cardiovascular disease, which will be defined as:

1. cardiac vascular disease;

2. cerebral vascular disease;

3. peripheral vascular disease;

before the age of 40 years.

Furthermore, all of these subjects must have a positive family history for cardiovascular disease. This will be defined as at least one first degree or two or more second degree family members with cardiovascular disease before the age of 55 for men and before the age of 60 for women.

1. Cardiac disease was defined when a subject has had a premature myocardial infarction as diagnosed as such by a cardiologist in the hospital, or a coronary artery bypass graft (CABG)surgery had occurred or has had coronary abnormalities on cardiac catheterization with or without percutanues transluminal coronary angiography (PTCA);

2. Cerebral disease was defined when a subject has had a young stroke or transient ischemic attack (TIA) as diagnosed as such by a neurologist in the hospital.

3. Peripheral vascular disease was defined when a subject has had peripheral arterial occlusive disease as diagnosed as such by a vascular surgeon or a percutaneous transluminal angiography or bypass surgery had occurred.

Controls:

Controls will be defined as healthy in case they have:
1. no cardiovascular history, such as no cardiac, cerebrovascular or peripheral artery disease;

2. no complaints of angina, claudication or TIA;

3. no family history for cardiovascular disease;

4. they are between the age of 35 and 55 years old.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Cases:

Patients will be excluded if they have a positive history for:
1. hypertension;

2. diabetes mellitus;

3. other disease;

and in case of:

4. pregnancy;

5. lactating women;

6. if subjects are below the age of 18 years;

7. if subjects are unable to give informed consent.

Controls:

Controls will be excluded if they have had a:

1. myocardial infarction;

2. CABG;

3. PTCA;

4. stroke;

5. TIA;

6. peripheral occlusive disease;

7. complaints referring to one of these.

They are also excluded if they have a:

8. positive family history for cardiovascular disease;

9. history of diabetes;

10. hypertension;

11. hypercholesterolemia;

12. other disease.

Besides subjects will be excluded in case of:

13. pregnancy;

14. lactating women;

15. if subjects are below the age of 18 years;

16. if subjects are unable to give informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	03-10-2007
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1029
NTR-old	NTR1061
Ander register	: 07-2-041
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

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