Potential of patient derived vascular cells for usage in vascular tissue engineering

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Primary Objective: a) Do EC/SMC from patients with cardiovascular disease and renal failure have inferior reproductive capacity compared to cells from control donors?Secondary Objectives: a) What is the interindividual variation of cultured...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON38188

Source
ToetsingOnline

Brief title
Patient derived cells for vascular tissue engineering

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
blood vessel disease, vascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiovascular disease, Endothelial Cells, Smooth Muscle Cells, Tissue Engineering

Outcome measures

Primary outcome

During in vitro cell culturing, basic characteristics will be determined and functional tests in high-throughput assays will be performed. The main endpoint will be reproductive capacity of each badge of cells.

Secondary outcome

Secondary parameters will be cellular adhesion and thrombogenicity for EC and extracellular matrix production for SMC. Besides the cellular in vitro assays, biomarkers for endothelial dysfunction will be measured in plasma. We aim to measure sICAM, sVCAM, vWF and thrombomodulin. Based on the outcomes of above mentioned assays, interindidivual variability will be determined by calculating the coefficient of variation.

Study description

Background summary

Vascular tissue engineering (TE) aims to develop a functional small diameter vascular graft as a replacement of coronary and peripheral arteries or for vascular access. Based on a biodegradable scaffold, seeded with autologous cells, these grafts promise better patency then prosthetic materials or even venous conduits. Within the field of vascular TE, primary endothelial cells (EC) and smooth muscle cells (SMC) of venous origin are widely used for seeding tubular constructs before implantation. For succesfull clinical translation it will be of uttermost importance to define the potentials of patient derived cells for TE before setting up the animal models and related studies.

Study objective

Primary Objective:
a) Do EC/SMC from patients with cardiovascular disease and renal failure have inferior reproductive capacity compared to cells from control donors?
Secondary Objectives:
a) What is the interindividual variation of cultured endothelial cells (EC) of a sick and a control population, regarding cellular reproductive capacity, adhesion, anti-thrombogenic and immunologic properties?
b) Can in vitro performance (see a.) and thrombogenicity of patient derived EC be predicted by circulating biomarkers of endothelial dysfunction in peripheral blood?
c) What is the interindividual variation of cultured SMC of a sick and a control population, regarding cellular reproductive capacity and matrix production?

Study design

The potential of patient derived vascular cells will be investigated in a case-control study, with two different patient groups. Vascular cells from relatively age/matched control objects without cardiovascular disease will serve as controls.

Study burden and risks

One blood sample will be drawn by means of venapuncture, and tissue sampling of rest material will be carried out during regular surgical procedures under anesthesia. No additional risk is involved with participation in this study. We have chosen these patient groups because this the target population for future application of vascular tissue engineering.

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

All groups: Age>18 years
Group A: Patients undergoing elective bypass surgery for coronary arterial disease in which the saphenous vein is used as bypass graft.
Group B: Patients receiving an AV-shunt in which a native arm vein is used for creation of the loop and which are having renal failure. Patients undergoing kidney transplantation.
Group C: Age/sex-matched patients undergoing surgical procedures in which small vessels are usually ligated or removed. Examples of these surgical procedures include thyroidectomy, inguinal hernia repair, or sarcoma resection.

Exclusion criteria

All groups: Age <18 years
Patients who will not provide informed consent.
Group C: History of cardiovascular disease, e.g. hypertension, hypercholesterolemia, diabetes, angina pectoris, myocardial infarction, cerebrovascular accident or peripheral arterial disease and chronic kidney disease. Smoking, or history of smoking in the last 15 years.

Study design

Design

Study type:	Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2010
Enrollment:	95
Type:	Actual

Ethics review

Approved WMO Date:	18-05-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-06-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-01-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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
CCMO	NL31333.068.10