Blood Outgrowth Endothelial Cells (BOECs) to study endothelial metabolic pathophysiology in diabetes patients.

Published: 05-06-2018
Last updated: 12-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational invasive

Summary

ID

NL-OMON46605

Source
ToetsingOnline

Brief title
Diabetes induced endothelial metabolic changes.

Condition

- Diabetic complications
- Nephropathies

Synonym
diabetes, diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: nierstichting binnen glycotreat consortium

Intervention

Keyword: Blood Outgrowth Endothelial Cells, Type 2 diabetes

Outcome measures

Primary outcome

Cell metabolism, endothelial maturation markers and angiogenic markers.

Secondary outcome

nvt

Study description

Background summary

Micro- and macrovascular complications are the pathological hallmarks of diabetes mellitus. Diabetic nephropathy is one of the most serious microvascular complications associated with diabetes and the incidence of type 2 diabetes (T2DM) is rapidly increasing. Despite better regulation of hyperglycemia and blood pressure, many patients still develop end-stage renal disease (ESRD). Worldwide, the number of patients with end-stage kidney disease necessitating dialysis or transplantation is reaching epidemic proportions. Therefore, innovative models that can advance our understanding of kidney disease and the potential for endogenous kidney regeneration are warranted. Currently various attempts are underway to create kidney-organoids using human pluripotent stem cells (hPSC) and strategies to control and guide the resulting development of these hPSC-derived kidney tissues will be crucial for future regenerative medicine applications. One of the main bottlenecks in differentiation and maturation of each nephrologic segment is early presence of a competent vasculature. One potential candidate for creation of endothelial cells is the blood-outgrowth endothelial cell (BOEC).

Study objective

1. To establish optimized and standardized approaches for the isolation and characterization of BOECs in control and diabetic patients.
2. To test whether the phenotype of BOECs cultured from blood of diabetic patients are significantly different than the phenotype of cultured BOECS from healthy persons.
3. To explore whether these BOECs phenotypic changes in diabetes are related only to environmental cues (plasma) or also results into epigenetic changes.

4. To develop in vitro strategies to use BOECs in the *nephron-on*a*chip* model to test for vascularization under control or diabetic circumstances.
5. To further develop the nephron*on*a*chip model with a vascularized glomerulus under control- or diabetic conditions for drug screening, disease modelling and regenerative kidney medicine.

Study design

The study is a non-therapeutic, basic science, experimental in vitro study that requires the sampling of venous peripheral blood of the participants for the isolation of BOECs and plasma. In addition, urine will be collected for inflammatory marker analysis.

Study burden and risks

The objectives of this study can only be reached by studying diabetes patients and healthy controls. The participants do not directly benefit from this research, however the burden is minimal as it is restricted to a venipuncture of negligible risk.
Participants may be requested for repeating sampling, only after new informed consent is asked.

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

In order to be eligible to participate in this study, the following criteria must be met:
- Age 18 years or older.
- Prior diagnosis of type 2 diabetes mellitus.
- Subject is willing to participate in the study, must be able to give informed consent and the consent must be obtained prior to any study procedure.;Healthy Controls
- Age 18 years or older, participants will be age-matched with recruited patients.
- Not known with type 2 diabetes mellitus

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Any concurrent illness, disability or clinically significant abnormality that may, as judged by the investigator, affect interpretation.
- Non-diabetic renal disease e.g. known polycystic kidney disease.
- Prominent renal deterioration (CKD-EPI *60 ml/min/1.73m²)
- Use of LMW heparin and/or immunosuppressive drugs.
- Signs of active infection or autoimmune disease, requiring systemic treatment.
- A psychiatric, addictive or any disorder that compromises ability to give truly informed consent for participation in this study.
- Use of any investigational drug.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2018
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	05-06-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL64597.058.18