FDG-PET CT scan: an additional tool in detection of peripheral arterial disease and its compensatory capacities in patients with diabetes type 2, an observational pilot study.

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1. FDG PET scanning will permit evaluation of atherosclerotic disease in lower limbs (both density and activity of macrophages in local plaques) in patients with diabetes type 2 2. To obtain a more precise identification of ischemic borders...

| Ethical review | Approved WMO |
|-----------------------|---|
| Status | Pending |
| Health condition type | Arteriosclerosis, stenosis, vascular insufficiency and necrosis |
| Study type | Observational invasive |

Summary

ID

NL-OMON33453

Source ToetsingOnline

Brief title FDG-PET scan in peripheral arterial disease in diabetes type 2

Condition

• Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

atheroslerosis, peripheral arterial disease

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diabetes, FDG-PET CT scan, peripheral arterial disease

Outcome measures

Primary outcome

1. Assessment of FDG uptake by PET imaging along plaques in the distal

vasculature of the lower limbs that is compared with presence of

atherosclerotic lesions within the same individual (as determined by

conventional CT scanning).

2. Difference in the distribution of FDG uptake by endothelium (at baseline vs.

after temporary occlusion by use of a tourniquet for 3 minutes) for each

predefined segment along the distal vasculature.

Secondary outcome

1. To evaluate whether FDG uptake significantly correlates to vascular plaques

on CT

2. To evaluate whether a FDG PET-derived ischemic border zone correlate with

conventional clinical scores of ischemia

Study description

Background summary

A significant reduction in microvascular disease is attained due to recent efforts in both screening programmes and therapy in patients with type 2 diabetes. Despite this success, major cause of both morbidity and mortality in

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type 2 diabetes is currently macrovascular disease with its ischemic complications. New developments in the field of nuclear medicine will extend opportunities to evaluate tissue structures through its functional properties (isotope scanning) and no more just its anatomical borders (CT scanning). Combination of both functionality and anatomy may give rise to new approaches that test tissue viability and this modality may be of great support in the evaluation of microvasculature and macrovasculature in high risk cardiovascular patients, like in the presence of type 2 diabetes. In regions of local ischemia and its borderzones along the vasculature, arteriogenesis is sprouting as a local rescue mechanism and with detection of these regions we may identify regions in which vessel re-growth is permissive with a subsequent repair of impaired circulation. Within some time, several therapeutic interventions are expected to be introduced (such as fibroblast growth factor (FGF)) interventions, actually in phase II clinical research) and a tool, such as fluorodeoxyglucose (FDG) PET CT scanning could be useful in evaluation of follow up after intervention with these new compounds.

Study objective

1. FDG PET scanning will permit evaluation of atherosclerotic disease in lower limbs (both density and activity of macrophages in local plaques) in patients with diabetes type 2

2. To obtain a more precise identification of ischemic borders concerning critical limb ischemia along the vasculature of the lower limb in patients with diabetes type 2.

Study design

Pilot observational study

Study burden and risks

Each participant will be submitted to radiation burden by the use of FDG PET/CT scanning. However, to reduce the radiation dose, only low-dose CT scans will be acquired, and the total amount of radiation exposure will be limited to approximately 10.4 mSv). Moreover, no intravenous or oral CT-contrast will be used. The use of the tourniquet is not described as harmful and this method has been used for several times in the clinical work-up of significant impaired distal circulation. If a functional anatomical evaluation method will become available to the clinic, a better scoring of the diabetic microvasculature and macrovasculature could be performed and this can be of enormous support during the clinical follow up after therapeutic interventions and during preparation of invasive procedures to restore optimal distal flow.

Contacts

Public Academisch Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

type 2 diabetes, presence of an threatened distal circulation no smoking.

Exclusion criteria

pregnancy or an actual wish for pregnancy lactation period less than a year in the postmenopausal state HbA1c > 11%

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at random glucose level more than 12 mmol/l at time of FGDPET scan.

Study design

Design

| Study type: | Observational invasive |
|---------------------|---------------------------------|
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

Recruitment

| NL | |
|---------------------------|-------------|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-03-2009 |
| Enrollment: | 14 |
| Туре: | Anticipated |

Ethics review

| Approved WMO | |
|--------------------|--------------------|
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

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

ССМО

ID NL26561.018.09