Imaging disease activity in patients with Graves' orbitopathy using [18F]-FDG-PET/CT - a pilot study

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To determine whether 18FGD-PET/CT imaging is able to show difference in [18F]-FDG uptake in orbital tissue between patients with active and inactive GO.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thyroid gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON38026

Source
ToetsingOnline

Brief title
GO-PET pilot

Condition

- Thyroid gland disorders
- Ocular infections, irritations and inflammations
- Autoimmune disorders

Synonym
Graves' orbitopathy; Thyroid-associated eye disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: fondsen

Intervention

Keyword: FDG-PET/CT, Graves' orbitopathy, Thyroid associated eye disease

Outcome measures

Primary outcome

Qualitative assessment of [18F]-FDG uptake in orbital tissue as imaged by the

PET/CT scan and comparison of data between subjects (or groups)

Secondary outcome

Semi-quantitative analysis of [18F]-FDG uptake as imaged by the PET/CT scan (a

standardized uptake value (SUV) is calculated)

Clinical Activity Score

Study description

Background summary

The assessment of disease activity in patients with Graves' orbitopathy (GO) is important in deciding who and when to treat, with what treatment modality. [18F]-fluorodeoxyglucose (FDG) positron emission tomography (PET) / computed tomography (CT) is an imaging technique for the assessment of metabolic activity. This technique is able to locate and identify inflammatory tissue. Since GO is an inflammatory disease, the orbital tissue is expected to show an increased FDG uptake. The value of FDG-PET/CT imaging in detecting, grading and monitoring GO has not yet been determined. This study will investigate whether 18FGD-PET/CT imaging is able to show difference in [18F]-FDG uptake in orbital tissue between patients with active and inactive GO.

Study objective

To determine whether 18FGD-PET/CT imaging is able to show difference in [18F]-FDG uptake in orbital tissue between patients with active and inactive GO.

Study design

Pilot study (observational case study)

Study burden and risks

The [18F]-FDG-PET/CT scan will be performed only once. Patients are not allowed to eat 6 hours prior to the scan. During the 60 minute waiting period patients will be asked to watch a video screen in order to minimize the difference in eye movements between patients.
There is a risk of the development of a hematoma at the site where the venous canule is inserted. No adverse effect events are to be expected during the [18F]-FDG-PET/CT scanning. The total effective radiation dose is calculated at 4.3 mSv, this complies with category II-B of the international guidelines IRCP 62.
The ophthalmological evaluation is part of the routine medical treatment and an extra inconvenience only for 3 out of 9 patients. For them it is not an unknown procedure: all patients in group 3 have had this (or a similar) evaluation in the past.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

> 18 years old and signed informed consent
Patients with Graves' orbitopathy (3 groups: higly active / moderately active / completely inactive)
Euthyroid >= 2 months

Exclusion criteria

Pregancy
Uncontrolled diabetes mellitus, or hyperglycemia prior to scan
For patients with active disease: currently receiving treatment for orbitopathy, or treatment ended < 3 months before entry
For patients with completely inactive disease: history of surgical decompression treatment

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2012
Enrollment:	9
Type:	Actual

Ethics review

Approved WMO

Date:	02-12-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-12-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL37324.042.11