Giant cell arteritis in sight - Imaging techniques in the ZGT GET cohort

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON49395

Source
ToetsingOnline

Brief title
Giant cell arteritis in sight

Condition

- Vascular disorders NEC

Synonym
Giant cell arteritis

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Source(s) of monetary or material Support: Pioneers in Health Care (PIHC) Website: https://www.utwente.nl/nl/techmed/innovatie/fondsen/pioneers-in-healthcare/over-pihc/

Intervention

Keyword: diagnostics, giant cell arteritis, imaging

Outcome measures

Primary outcome

The diagnosis after 6 months.

This will be used to calculate the sensitivity, specificity and AUC to evaluate

the validity of the three imaging techniques. These values can then be compared

for the three imaging techniques

Secondary outcome

The diagnoses after 6 months follow-up

This will be used to calculate the sensitivity, specificity and AUC to

evaluate the validity of the temporal artery biopsy. This can then also be

compared to these values from the three imaging techniques

Study description

Background summary

Giant cell arteritis (GCA) is a large vessel vasculitis with potentially devastating complications that can be prevented when treatment is started as soon as possible. The affected population is older than 50 years with a peakincidence above 70 years. It is a rare disease with an incidence of 1 in 10000 personyears. The typical presentation is a new onset headache, mostly temporally located, jaw claudication and certain visual symptoms combined with pain over the temporal artery, decreased pulsations and elevated inflammatory markers. Less known is the presentation with symptoms such as fever and weight loss. Visual loss, cerebrovascular accidents and aneurysms of the aorta are the potential complications of GCA. These complications can be prevented by a timely treatment with corticosteroids. Unfortunately, corticosteroids have many side effects leading to a significant impact of the disease even when treated adequately. So, there is a need for an early and accurate diagnosis, which is difficult with the current standard of care. The elevated inflammatory markers

(ESR and CRP) are aspecific, and a biopsy of the temporal artery is not very sensitive as well as invasive and with a delayed result. Until now the biopsy is regarded the golden standard due to a lack of a better test. Meanwhile, non-invasive imaging techniques are emerging, such as ultrasound sonography, MRI/MRA and FDG-PET/CT. These are quick and may aid during the course of GCA. Compared to the biopsy, recent literature has shown some promising results for these techniques. However, due to a lack of a direct comparison between the three techniques the question remains which one is best to diagnose GCA.

To aid early diagnosis of GCA, the current research project was initiated in a collaboration between the Ziekenhuisgroep Twente (ZGT) and the University Twente (UT).

Study objective

The overall aim is to improve therapy and prognosis in patients with GCA by improving the diagnostic process. We wish to do so by comparing 3 imaging techniques in a cross-sectional manner. The following goal was formulated:

To compare validity and accuracy of ultrasound sonography, FDG-PET/CT and MRI/MRA with each other in comparison to the reference standard for the study; the diagnosis of the rheumatologist after 6 months.

Study design

Nested-case control study within a cohort (ZGT GET cohort)

Study burden and risks

Two imaging techniques (FDG-PET/CT and MRI/MRA) will be performed in addition to ultrasound sonography as ultrasound sonography is already a part of our usual care at baseline. Both FDG-PET/CT and MRI/MRA are used often in the usual care of other diseases. As information flyers are available for both FDG-PET/CT and MRI/MRA from usual care, patients in our study will also receive these flyers in addition to the study information. Contraindications for both imaging techniques will be applied. If these are used, the risks of both imaging techniques are negligible. Ultrasound sonography is harmless. For FDG-PET/CT and MRI/MRA certain agents are used, but these hardly have side effects. Furthermore, the radiation load is low - about 4,5 mSv - and not harmful for the patient or his or her environment. No iodine agents will be used and a low dose CT will be done.
We therefor do not expect any additional risks with this study, however, there is a significant time burden on patients. The FDG-PET/CT procedure can take up to 3 hours and a MRI/MRA 30-45 minutes. For both an intravenous line is necessary. Unfortunately there is no other way to address this research question. A RCT or cohort comparing these imaging techniques by comparing

(similar) patients groups is not possible due to the need for large patient populations for these types of studies. As GCA is a rare disease these patient populations are not possible. Nonetheless, there is a need to compare these imaging techniques to better use imaging techniques in the diagnosis of GCA in the future. Perhaps the current study may even contribute to the reduction of temporal artery biopsies for the diagnosis of GCA.

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

Patients with a suspicion of GCA (based on the suspicion of the treating rheumatologist or the referring general practitioner)

Exclusion criteria

- Contra-indications, as used in regular care, for the imaging techniques used (FDG-PET/CT of MRI/MRA)
- Legally incapable

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):	17-07-2020
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	06-03-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL71488.100.19