# Tackling underdiagnosis of Large Artery Giant Cell Arteritis: a prevalence and phenotype study.

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

# Summary

### ID

NL-OMON35072

**Source** ToetsingOnline

**Brief title** Prevalence of large artery giant cell arteritis

### Condition

• Vascular disorders NEC

**Synonym** giant cell arteritis, large vessel vasculitis

**Research involving** Human

### **Sponsors and support**

**Primary sponsor:** Vrije Universiteit Medisch Centrum **Source(s) of monetary or material Support:** Rheumafonds

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### Intervention

Keyword: arteritis, giant cell, PET/CT

#### **Outcome measures**

#### **Primary outcome**

Prevalence of large-vessel-vasculitis in patients with temporal arteritis or

unexplained prolonged inflammatory response.

Diagnostic utility of PET/low-dose-CT in patients with an unexplained prolonged

inflammatory response.

#### Secondary outcome

Association between large-vessel-vasculitis and clinical/biochemical parameters.

Association between large-vessel-vasculitis and inflammation score of temporal

artery biopsy.

Sensitivity and specificity of temporal artery biopsy for

large-vessel-vasculitis.

Association between FDG-uptake and vessel wall morphology/lumen morphology.

# **Study description**

#### **Background summary**

Inflammation of an artery in the region of the temple is the cause of temporal arteritis with complaints being new onset headache, jaw claudication and an elevated erythrocyte sedimentation rate. Temporal arteritis is a subset of giant cell arteritis and is more and more thought to be associated with extracranial large-vessel-vasculitis. The aorta and its major branches are mainly affected. Varying imaging techniques such as PET, MRI and CT, have been used to assess large vessel inflammation in patients suffering from temporal arteritis. However, the exact prevalence of large-vessel-vasculitis in these patients has not been studied well and therefore is not known. Using the above-mentioned imaging techniques large-vessel-vasculitis has been diagnosed in patients with symptoms not suggestive of temporal arteritis but a more systemic inflammatory response with an unexplained elevated erythrocyte sedimentation rate. This could be a reason to screen patients with a systemic inflammtory response of unknown origin using PET/CT. In this selected group, however, the prevalence of large artery inflammation is also unknown. Previous studies have tried to correlate large-vessel-vasculitis with clinical and biochemical parameters. None of the studied parameters could have been assessed as a predictor of large artery inflammation.

#### Study objective

The primary objectives of the study are to assess the prevalence of large artery inflammation in patients with temporal arteritis or an unexplained inflamatory response and the diagnostic utility of 18FDG-PET/CT in patients with an unexplained inflammatory response.

Secondary objectives are to determine clinical and/or biochemical factors that could predict large artery inflammation and to determine sensitivity and specificity of a temporal artery biopsy in patients with large-vessel-vasculitis.

### Study design

Temporal arteritis patients or patients with an unexplained prolonged inflammatory syndrome will be included from the VU medical centre or one of its affiliated hospitals. Informed consent will have to be signed. A history will be taken and physical examination wil be performed. Blood will be drawn (and stored first for practical reasons, only after patient's approval) to be able to determine the association between biochemical parameters and large-vessel-vasculitis. Some blood will be saved for possible future DNA-research. Imaging studies for temporal arteritis patients comprise of a PET/high-dose-CTa and for patients with an unexplained prolonged inflammatory syndrome a PET/low-dose-CT. Finally a temporal artery biopsy will be taken from the temporal arteritis patients and from the patients with unexplained inflammatory syndrome with a PET/CT compatible with large-vessel-vasculitis and the first 10 patients whose PET/CT is not compatible with large-vessel-vasculitis.

#### Study burden and risks

Risk:

Possibility of an anaphylactic reaction for patients undergoing
PET/CT-Angiography as a result of iodinated contrast administration.
Burden:

- One extra visit to the hospital.

- Temporal artery biopsy in patients with an unexplained elevated ESR who have no signs of large-vessel-vasculitis: it's a minor invasive procedure with a small chance of complications.

- Higher radiation dosage for patients undergoing PET/CT-Angiography.

- The drawing of blood samples (total of 5 samples at 1 occasion) might lead to

a hematoma, slight pain at the insertion site during, and after the insertion,

as well as the risk of failure and thus repetitive attempts.

# 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**

Giant cell arteritis according to the 1990 ACR classification critieria, or elevated ESR on 2 separate occasions with a time interval of at least 4 weeks, the elevated ESR is not explained by a chest radiograph, abdominal ultrasound or blood tests (including paraprotein testing)

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### **Exclusion criteria**

The use of corticosteroids or any other systemic immunosuppresant for more than 24 hours at the time of PET-CT scanning. Inability to understand or unwillingness to provide informed consent. A plasma glucose level >11 mmol/l at the time of PET-CT scanning.

# 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):	09-09-2010
Enrollment:	100
Type:	Actual

# **Ethics review**

Approved WMO	
Date:	12-08-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

# **Study registrations**

### Followed up by the following (possibly more current) registration

No registrations found.

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# Other (possibly less up-to-date) registrations in this register

No registrations found.

# In other registers

Register

ССМО

ID NL31539.029.10