

# Is there a role for duplex ultrasound in patients with a clinical suspicion of temporal arteritis?

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Determining the role of duplex ultrasound in patients with a clinical suspicion for temporal arteritis. Determining the sensitivity, specificity, negative predictive value and positive predictive value of duplex ultrasound in patients with a clinical...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Autoimmune disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON45043

### Source

ToetsingOnline

### Brief title

Duplex ultrasound in patients with clinical suspicion of temporal arteritis

### Condition

- Autoimmune disorders
- Vascular disorders NEC

### Synonym

arteritis cranialis, Giant cell arteritis, granulomatous arteritis, Horton disease, Temporal arteritis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medisch Centrum Alkmaar

**Source(s) of monetary or material Support:** geen

## Intervention

**Keyword:** Arteritis, Duplex, Temporal, Ultrasound

## Outcome measures

### Primary outcome

To determine the sensitivity, specificity, negative predictive value and positive predictive value of duplex ultrasound in patients with a clinical suspicion for temporal arteritis.

### Secondary outcome

To determine the best hierarchy from the different diagnostic tools. We will compare the differences in sensitivity on these.

## Study description

### Background summary

Temporal arteritis is a form of vasculitis on which the branches of the temporal artery superficial are affected. The disease can go hand in hand with a large variety of clinical symptoms. In the past, irreversible loss of sight occur to 35-60% of the patients. Due to fast diagnosing and adequate treatment, the risk on losing sight is decreased to 7-14%. The disease will be treated with a large amount of corticosteroids. These steroids can cause serious side effects. Therefore it is very important to determine if a patient has the disease or not.

Beside the clinical review, a biopsy of the temporal artery is currently the gold standard to determine temporal arteritis. Although the biopsy is relatively safe, there are some potential risks like woundinfection, damage on the facial nerve, CVA due to interruption in the collateral circulation and necrosis of the temporal scalp. Recently, a number of studies have been done to determine the value of duplex ultrasound in patients with suspicion for temporal arteritis. With duplex there is no risk of complications, no use of ionizing radiation, relatively easy and fast achievable, and cheap. Most of the published articles confirm the high specificity and a bit lower sensitivity for

duplex on patients with suspicion for temporal arteritis. The question is what the value of duplex ultrasound is in patients with clinical suspicion for temporal arteritis in the MCA. It is also the question what the ideal location for duplex ultrasound is in the diagnostic course for these patients.

## **Study objective**

Determining the role of duplex ultrasound in patients with a clinical suspicion for temporal arteritis.

Determining the sensitivity, specificity, negative predictive value and positive predictive value of duplex ultrasound in patients with a clinical suspicion for temporal arteritis compared to the reference standard. This in comparison with the diagnostic accuracy of the biopsy compared to the reference standard. We defined the reference standard as the definitive diagnosis one year after inclusion, jointly composed by the physicians.

## **Study design**

This is a per prospective study.

Patients with symptoms which could be explained by temporal arteritis will be included in the study in accordance with the internist or rheumatologist. After that the following steps will be taken:

1. Clinical a priori estimate for presence of large vessel vasculitis
2. Duplex ultrasound (presence of halo, stenosis and/or occlusion)
3. Questionnaire from patients (complaints, characteristics of the disease, use of medicine, demographic characteristics)
4. When performed: biopsy
5. The diagnosis after 1 year (blinded evaluated by an internist as well as by a rheumatologist, and the final diagnosis as drafted by these clinicians jointly.)

## **Study burden and risks**

Patients are offered a duplex ultrasound and a mini-questionnaire will be submitted. Therefore we will request half an hour of their time. Risks for patients are negligible.

## **Contacts**

### **Public**

Medisch Centrum Alkmaar

Wilhelminalaan 12  
Alkmaar 1815JD  
NL  
**Scientific**  
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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Clinical suspicion of temporal arteritis

### Exclusion criteria

Treatment with corticosteroids longer than 1 week

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 28-04-2017  
Enrollment: 300  
Type: Actual

## Medical products/devices used

Generic name: Ultrasound machine  
Registration: Yes - CE intended use

## Ethics review

Approved WMO  
Date: 12-04-2017  
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	ID
CCMO	NL46986.094.15