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

Published: 12-04-2017
Last updated: 14-04-2024

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	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 goes 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 save, there a 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 achieveble, and cheap. Most of the publiced 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.

Determing 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 of 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 medicin, demographic characteristics)
4. When performed: biopsy
5. The diagnosis after 1 year (blinded evalueted by an internist as well blinded evalueted by an 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

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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 then 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