David against Goliath - Use of microbubbles and more to improve the diagnostics of Giant Cell Arteritis. A pilot study

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

Summary

ID

NL-OMON56660

Source
ToetsingOnline

Brief title
David against Goliath - Use of microbubbles and more for GCA

Condition

- Vascular disorders NEC

Synonym
Giant cell arteritis; large vessel vasculitis

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente

Source(s) of monetary or material Support: Er is een wetenschapsvoucher vanuit het ZGT waaruit een deel van de personeels kosten vergoed is bij de voorbereiding van de studie.

Intervention

Keyword: 3D, CEUS, SMI, Ultrasound

Outcome measures

Primary outcome

The primary endpoint will be the diagnostic value of the techniques, calculated using the sensitivity and specificity, including the AUC, the positive predictive value and negative predictive value.

Secondary outcome

The secondary endpoints are the interobserver variability (calculated using Cohen's kappa dichotomous outcomes and the intraclass coefficient for continuous outcomes), and the duration in minutes.

Study description

Background summary

Giant cell arteritis (GCA) is the most common form of vasculitis and can lead to serious complications such as acute blindness and ischemic cerebrovascular accidents (iCVAs). Prompt initiation of corticosteroid treatment can prevent complications, making prompt diagnosis essential. However, overtreatment must be avoided, as corticosteroids can cause side effects in > 80% of patients. Nowadays, ultrasound is increasingly used to make the diagnosis. However, the sensitivity of the study, the duration of the study (at least 45 minutes), investigator dependence, and the limited value during follow-up leave room for improvement. Current techniques that can be added to conventional ultrasound, used for other conditions, such as contrast enhanced ultrasound sonography (CEUS), 3D ultrasound (3D) and superb microvascular imaging (SMI) may improve the current ultrasound of the vessels in GCA with the potential to not only improve diagnostics, but also the monitoring of GCA activity during follow-up.

Study objective

The primary aim of this study is to evaluate 3 techniques (CEUS, 3D and SMI), that can perhaps improve the ultrasound assessment of GCA with regard to its diagnostic value when applied alone or in combination. The hypothesis is that the diagnostic value will improve following the addition of the techniques individually or as a combination. Secondary objectives are to assess the interobserver variability (as measure of reliability) for the three techniques alone or in combination in the assessment of GCA. The hypothesis is that these can also be improved. For 3D ultrasound, the time reduction compared to conventional ultrasound will be assessed, as a time reduction is only expected for this technique.

Study design

This study is a cross-sectional pilotstudy

Study burden and risks

The techniques that will be tested in this study can potentially contribute to improving the diagnostic value of ultrasound in GCA. A better diagnostic value allows for rapid and accurate treatment, reducing the risk of irreversible complications of GCA itself or of overtreatment using corticosteroids. Two of the techniques (3D and SMI) are add-ons to the ultrasound machine and pose no additional risks for patients. The third technique, CEUS, has a small risk (0.125%) of reversible side effects such as headache and nausea, and a very small risk (0.0086%) of an allergic reaction. The drug that will be used for CEUS, Sonovue, has been extensively researched and is used in regular care for ultrasound in cardiology. The risk for study participants is therefore minimal. The contribution to the study will not bring any personal benefit to the participants. They will contribute to the study for around 3 hours and receive an injection for the administration of Sonovue. Disease data will also be collected from participating patients.
In this pilot study, the 3 techniques will be tested seperately and simultaneously. The data from this study will show which (combination of) techniques are best suited for further research with regards to improving diagnosis and follow-up in patients with 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 and healthy controls 50 years or older
- no atherosclerosis with ischaemic complications
- sufficient understanding of the dutch language
Specificaly for patients:
- diagnosis RCA according to ACR/EULAR criteria 2022
- visible abnormalities consistent with RCA on conventional ultrasound sonography

Exclusion criteria

- legal incapacity
- use of corticosteroids for > 7 days at a dose of > 5 mg per day at the time of inclusion or in the month prior to the ultrasound
- contraindication for the use of microbubbles or 3D ultrasound

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	22-02-2024
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO Date:	22-03-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	11-07-2024
Application type:	Amendment
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	NL85501.100.23