ACR/EULAR endorsed study to develop classification and diagnostic criteria for primary systemic vasculitis

Published: 22-03-2011
Last updated: 30-04-2024

1. Validate and adjust the current classification criteria for systemic vasculitis2. Develop and validate new diagnostic criteria for systemic vasculitis

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

Summary

ID

NL-OMON36606

Source
ToetsingOnline

Brief title
ACR/EULAR diagnostic and classification criteria for vasculitis/DCVAS

Condition

- Autoimmune disorders
- Vascular disorders NEC

Synonym
vasculitis, vesselwall inflammation

Research involving
Human

Sponsors and support

Primary sponsor: Oxford university
Source(s) of monetary or material Support: The American College of Rheumatology;The European League Against Rheumatism;The Vasculitis Foundation

Intervention

Keyword: classification, criteria, diagnostic, vasculitis

Outcome measures

Primary outcome

See above

1. Model of criteria who can best classiffy patients with vasculitis into

different vasculitis subgroups.

2. Model of criteria who can beste distinguish patients with vasculitis from

the vasculitis mimic patients

Secondary outcome

n.a.

Study description

Background summary

Primary systemic vasculitides are auto-immune vessel wall inflammatory diseases and have an annual incidence of more than 100 new cases per million persons. All types of blood vessels can be involved and the clinical effects of vasculitis are therefore diverse. Today, these illnesses are classified according to the size of vessels involved (large, median, small), the type of inflammation observed in a biopsy (granulomatous, eosinophilic, etc.) and certain clinical characteristics like headache, age, renal involvement, etc. These classification criteria were developed in 1993. Classification criteria assume the presence of vasculitis and subsequently help categorize these vasculitides in different groups. Classification criteria in itself are not capable to distinguish vasculitis patients from patients without vasculitis. In order to achieve this diagnostic criteria are needed. At the moment there are no validated diagnostic criteria available for systemic vasculitis.
The availability of well validated diagnostic criteria will help clinicians diagnose patients earlier and with more accuracy. It can be expected that patients can then be treated more quickly and more efficiently. The chance of developing damage due to the disease will be reduced. Well developed diagnostic criteria also help better distinguish patients with vasculitis from those who

have complaints who look like vasculitis (the *vasculitis mimics*). The latter group requires different treatment.

Study objective

1. Validate and adjust the current classification criteria for systemic vasculitis
2. Develop and validate new diagnostic criteria for systemic vasculitis

Study design

Include patients with vasculitis and patients with other diseases who can mimic vasculitis. The available clinical, serological, pathological and radiological parameters will be recorded and analyzed. A multivariate analysis model will be developed who can identify the key factors distinguishing the various diseases. As part of this process, we will develop a series of vignettes based on different cases of which a group of international experts judges that they fit a certain type of vasculitis best. In this process existing classification criteria will be validated and possibly new criteria will be developed. Moreover, diagnostic criteria will be developed who best distinguish vasculitis patients from non-vasculitis patients (vasculitis mimics).

Study burden and risks

Twice extra time investment during an already planned hospital visit. (60 minutes total). Within this visit patients will be asked questions and if applicable be physically investigated. Extra blood will be drawn coupled to the already planned blood withdrawal.

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

• Adult patients aged >=18 years. There is no upper age limit.
• Ability to give informed consent.
• New presentation or an established diagnosis of Wegener's granulomatosis, microscopic polyangiitis, Churg Strauss syndrome, giant cell arteritis, Takayasu arteritis, other primary large vessel vasculitis or complaints that mimic these diseases.

Exclusion criteria

• Patients < 18 years of age
• Patient unwilling or unable to provide informed consent.
• Known co morbidity at time of presentation that explains the clinical presentation.
• Hepatitis B or C

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2011
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	22-03-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT01066208
CCMO	NL32107.042.10