

Cerebral Micro Emboli Signal Detection in Endocarditis. A prospective follow-up study

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The evaluate the value of the TCD in a selected patients group with a left-tailed endocarditis - treated in first case with antibiotic - to predict the chance of a CVA. The primary goal is to develop a prediction model.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Endocardial disorders
Study type	Observational invasive

Summary

ID

NL-OMON54754

Source

ToetsingOnline

Brief title

CMED

Condition

- Endocardial disorders
- Embolism and thrombosis

Synonym

endocarditis, micro embolie detectie, ontsteking van het weefsel van de hartkamer

Research involving

Human

Sponsors and support

Primary sponsor: HagaZiekenhuis

Source(s) of monetary or material Support: subsidie wordt gevraagd voor de extra MRI

aan het wetenschapsfonds van het HagaZiekenhuis

Intervention

Keyword: Endocarditis, Micro Emboli Signal (MES) detection

Outcome measures

Primary outcome

Primary endpoint: development of a CVA during the hospitalization

Secondary outcome

Secondary neurological endpoints are:

1. The severity of the CVA at origin and after 3 months (NIHSS score), the type of CVA (ischemic or hemorrhage)
2. Occurrence of TIA's,
3. Occurrence of meningitis,
4. developing a cerebral abscess/cerebritis,
5. mortality,
6. functional outcome after 3 months
7. SWI/DWI/Flair and T2 lesions on MRI brain (after 3 months or <24h prior to surgery) in compare with inclusion MRI.
8. Occurrence of a heart surgery or valve surgery after inclusion.

Study description

Background summary

Although endocarditis is relatively rare (incidence between the 1.5-11.6/100,000 person years), the disease is still a great burden to public health endocarditis as a disease with a high mortality and morbidity. The mortality in an infective endocarditis is on average around the 15-20% [1.2],

rising to 80% at the presence of Staphylococcus Aureus/heart failure/annulusabces.

Complications of endocarditis could be manifest locally in the heart itself (abscesses/aneurysms/fistulas), but also peripheral including septic embolization to other organs. Embolic complications, such as developing a cerebral infarction, is associated with a greatly increased risk of mortality. Ultrasound of the heart is not only important for the diagnosis endocarditis, but also an important part of the risk determination to getting complications. The risk stratification with echocardiography is not sufficiently reliable to predict the risk of systematic and cerebral embolic complications.

Technology Doppler (TCD-Doppler) can detect micro-emboli signals (MES). This method is shown in several studies to be effective in patients with acute cerebral infarction, symptomatic carotid stenosis and post-operative after a carotisendarteriectomy in predicting high-risk patients developing a stroke recurrence. TCD-Doppler technology seems to be of great value in identifying a subpopulation that, despite antibiotic therapy, is at high risk of embolic complications.

Study objective

The evaluate the value of the TCD in a selected patients group with a left-tailed endocarditis -treated in first case with antibiotic - to predict the chance of a CVA. The primary goal is to develop a prediction model.

Study design

This will be a prospective, observational study with micro embolic signal detection in patients with recently a left-tailed endocarditis diagnosis and the treatment will be primary antibiotic.

Micro embolic signal detection with TCDx will unilaterally take place within 3-5 days after diagnosis. At inclusion and after 12 weeks is an MRI with certain sequences (the so called diffusion weighted imaging [DWI] and the susceptibility weighted imaging [SWI]), this makes it possible to recent subclinical ischemic CVA's (with DWI sequences) or micro hemorrhages (with SWI sequences). MRI will also be done with a Flair and T2 setting to not recent ischemia to quantify. Patients who have to undergo surgery for the endocarditis, will receive their second MRI <24hours prior to the surgery.

Study burden and risks

This study will be provide information if TCD embolism detection can be used in risk stratification of the occurrence of a embolic CVA. There are no advantages or disadvantages for the patient. TCD research is an easy-to-use non-invasive analysis of the cerebral blood stream by ultra sound.

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

1. Proven left-tailed infective native endocarditis or bioprosthetic valves endocarditis
2. ultrasound test of the heart not older than 2 weeks
3. 18 years and older
4. mentally competent
5. written informed consent

Exclusion criteria

1. right-tailed endocarditis
2. left-tailed endocarditis with already an emergency indication for

- heartsurgery/valve replacement (<24h)
3. lack of a temporal window
 4. severe claustrophobia or other MRI contraindications
 5. Clinical manifestations of an old/recent CVA
 6. mechanical valve

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 15-02-2019

Enrollment: 100

Type: Actual

Medical products/devices used

Registration: No

Ethics review

Approved WMO

Date: 11-09-2018

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 20-02-2019

Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 18-03-2019
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 10-09-2019
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 03-04-2021
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 27-07-2021
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 23-05-2022
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 14-09-2023

Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 17-06-2024
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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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	NL66257.098.18