Improved Diagnostic Strategies in Staphylococcus aureus bacteraemia

Published: 10-07-2017
Last updated: 13-04-2024

Primary objectives1. Determine prospectively the accuracy of proposed clinical criteria to assess the risk of SA-IE and complicated SAB2. Determine the diagnostic accuracy of cCT for SA-IE in patients with SAB3. Determine the diagnostic and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Observational invasive

Summary

ID

NL-OMON49374

Source
ToetsingOnline

Brief title
IDISA

Condition

- Cardiac valve disorders
- Bacterial infectious disorders

Synonym
Endocarditis, sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Innovatiefonds Zorgverzekeraars

Intervention

Keyword: Bacteraemia, Diagnosis, Endocarditis, Staphylococcus aureus

Outcome measures

Primary outcome

Main cohort study:

1. Presence or absence of infective endocarditis and/or complicated SAB, as classified by study adjudication committee at the end of the study based on all clinical information up to 90 days after discharge.

cCT sub-study:

1. Diagnostic accuracy of cardiac CT for the diagnosis of endocarditis in patients with SAB.

qPCR sub-study:

1. Diagnostic accuracy of qPCR for the diagnosis of complicated SAB and SA-IE bacteraemia in patients with SAB.

Biobank sub-study:

1. The diagnostic and prognostic value of host response biomarkers during antimicrobial therapy for the diagnosis of complicated SAB and SA-IE

Secondary outcome

Main cohort study:

1. Diagnostic accuracy (sensitivity, specificity, positive and negative predictive values) of clinical criteria for the diagnosis of endocarditis

and/or complicated SAB

2 Exploratory analysis of differences in bacterial virulence factor expression between patients with uncomplicated SAB and patients with SA-IE and/or patients with complicated SAB.

3. Infection related mortality and morbidity, as classified by study adjudication committee at the end of the study based on all clinical information up to 90 days after discharge

4. Health care related costs up to 90 days after discharge.

5. Quality of life (as measured using EQ 5D 5L) on inclusion and 90 days after discharge.

cCT sub-study:

1. Cost-effectiveness of a cardiac-CT-for-all algorithm in patients with SAB, compared to normal diagnostic work flow.

2. Cost-effectiveness of a cardiac-CT algorithm only for patients classified as high-risk according to clinical criteria.

3. Patient comfort during cCT compared to TEE.

Study description

Background summary

Staphylococcus aureus bacteraemia (SAB) is a frequent cause of community and hospital-acquired infection. The clinical spectrum ranges from uncomplicated infection of an intravascular catheter to fulminant endocarditis with metastatic infection. Recognition of endocarditis (SA-IE) and other forms of complicated SAB is an important clinical issue, but there have been few advances in diagnostic tests. The IDISA study aims to improve diagnosis of

complications in patients with SAB by testing new, promising diagnostic modalities.

Study objective

Primary objectives
1. Determine prospectively the accuracy of proposed clinical criteria to assess the risk of SA-IE and complicated SAB
2. Determine the diagnostic accuracy of cCT for SA-IE in patients with SAB
3. Determine the diagnostic and prognostic value of serial bacterial load measurement(s) (quantitative PCR) for metastatic S. aureus infection
4. Find biomarkers for SA-IE and complicated SAB using a biobank
5. Identify bacterial virulence factors for SA-IE and complicated SAB

Study design

A multicentre prospective cohort study with one main cohort and three sub-studies. Patients can participate in as many sub-studies as they consent to.

These sub-studies are:

cCT sub-study
qPCR sub-study
Biobank sub-study

The biobank and qPCR sub-studies have two variants.
One variant includes one venapuncture after inclusion only

The other variant includes one venapuncture after inclusion and two subsequent venapunctures on day 3 and 7 after inclususion.

Study burden and risks

The main study involves no invasive measurement but patients are asked to fill in the EQ 5D 5L at inclusion and through telephone interview at 90 days after discharge.
Participants in the cCT study are subjected to 2-10 mSv of ionizing radiation and have a small risk of contrast induced nephropathy.

Participants in the qPCR and biobank-substudies are subjected to either one or three additional venepunctures during the first week after inclusion. Risks from venepuncture are limited to pain or discomfort during puncture and formation a hematoma.

Incapacitated persons are excluded from the cCT sub-study. The risks and burden for incapacitated patients for the main study and the qPCR and biobank sub-substudies are minimal and these patients can be included after informed consent by a legal representative. Excluding (temporarily) incapacitated patients from the main study or qPCR/biobank substudies would greatly limit generalizability and external validity of study results

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 6
Amsterdam Zuidoost 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 6
Amsterdam Zuidoost 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Positive bloodculture with Staphylococcus aureus

Exclusion criteria

For the main study and the qPCR and Biobank sub-studies: none., For the cCT substudy: eGFR <45ml/min, pregnancy, female <30 years, inability to provide informed consent, life-expectancy <4 weeks, hemodynamic instability or respiratory failure.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-07-2017
Enrollment:	526
Type:	Actual

Ethics review

Approved WMO Date:	10-07-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-01-2019

Application type:	Amendment
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
Other	26987 (Nederlands Trial Register)
CCMO	NL60653.018.17