

The value of F-18-fluorodeoxyglucose Positron Emission Tomography for detection of Metastatic Infectious foci complicating gram-positive bacteraemia

Submission date 02/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 02/05/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/10/2022	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

The value of F-18-fluorodeoxyglucose Positron Emission Tomography for detection of Metastatic Infectious foci complicating gram-positive bacteraemia

Acronym

MI-PET

Study objectives

F-18-fluorodeoxyglucose Positron Emission Tomography (FDG-PET) enables early and more accurate diagnosis of metastatic infection, resulting in a reduction of the number of relapses.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the local ethics board (CMO Regio Arnhem-Nijmegen at UMC St Radboud) on the 18th October 2005 (ref: CMO-nr:2005/149).

Study design

Multicentre, non-randomised, controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Metastatic infection/ gram-positive bacteraemia

Interventions

FDG-PET will be performed within 14 days after initiation of treatment. The attending physician will be informed of the results of FDG-PET immediately. Special attention will be paid to confirmation of FDG-PET results with conventional diagnostic procedures. Minimal patient follow-up will be until three months after the first positive blood culture.

In the analysis every prospectively included patient will be matched to a historic control, according to the micro-organism and the presence of specific risk factors summarised under the inclusion criteria. These historic controls are enrolled from the database of the department of Microbiology in our hospital between January 2000 and December 2004. All relevant data of this historic control group are retrieved from the patients charts and the hospitals electronic databases before patients are matched.

The retrospective database (control group) is expected to be completed June 2007. Matching between our prospective and retrospective patients will be three months after end of recruitment, in order to have a minimal three-month follow-up in all patients.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Relapse rate of infection

Secondary outcome measures

1. Attributable mortality
2. Mortality after relapse
3. Duration of first admission
4. Duration of antibiotic treatment
5. Number of diagnostic procedures performed to confirm metastatic foci, duration of admission due to relapse
6. Associated costs

Overall study start date

01/11/2005

Completion date

01/11/2007

Eligibility

Key inclusion criteria

1. All patients with blood cultures containing one of the following micro-organisms:
 - a. Streptococcus aureus
 - b. Streptococcus species (excluding S. pneumoniae)
 - c. Enterococcus species
2. AND at least one of the following risk factors for metastatic infection:
 - a. Community acquired infection
 - b. Signs of infection for more than 48 hours before initiation of appropriate treatment
 - c. Skin lesions or other symptoms or signs pointing to possible metastatic infection

- d. Fever lasting for more than 72 hours after initiation of appropriate treatment
 - e. Positive blood cultures for more than 48 hours after initiation of appropriate treatment
3. Informed consent

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

115

Key exclusion criteria

1. Age less than 18 years
2. Polymicrobial infection
3. Pregnancy
4. Critically ill patients initially admitted to the Intensive Care Unit (ICU) department for more than 14 days
5. Chemotherapeutically induced neutropenia

Date of first enrolment

01/11/2005

Date of final enrolment

01/11/2007

Locations**Countries of recruitment**

Netherlands

Study participating centre

Radboud University Nijmegen Medical Centre

Nijmegen

Netherlands

6500 HB

Sponsor information**Organisation**

University Medical Centre St. Radboud (The Netherlands)

Sponsor details

Department of Nuclear Medicine
Nijmegen
Netherlands
6500 HB

Sponsor type

Hospital/treatment centre

Website

<http://www.umcn.nl/homepage>

ROR

<https://ror.org/05wg1m734>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		01/12/2005		Yes	No
Other publications		01/02/2007		Yes	No
Results article		01/03/2012	25/10/2022	Yes	No