ISRCTN76425553 https://doi.org/10.1186/ISRCTN76425553

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

Registration date
02/05/2007

Overall study status
Completed

Last Edited
25/10/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr F.J. Vos

Contact details
Radboud University Nijmegen Medical Centre
Department of Internal Medicine, 463
P.O. Box 9101
Nijmegen
Netherlands
6500 HB
31 (0)24 361 4763
F.Vos@AIG.umcn.nl

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