ISRCTN72245261 https://doi.org/10.1186/ISRCTN72245261

Prevention of coagulase-negative staphylococcal central venous catheter-related infection using urokinase rinses: a randomised double-blind controlled trial in patients with haematological malignancies

Submission date
07/03/2007

Recruitment status
No longer recruiting

Registration date
07/03/2007

Overall study status
Completed

Last Edited
21/01/2008

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 M V Huisman

Contact details
Leiden University Medical Centre (LUMC)
Department of General Internal Medicine, C2-R
P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 625 9111
m.v.huisman@lumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Urokinase rinses will lead to less Coagulase-Negative Staphylococcal (CoNS) infections in patients with haematological malignancies and central vein catheters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, placebo controlled, parallel group, double blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Coagulase-negative staphylococcal central venous catheter-related infection

Interventions
Urokinase rinses of central vein catheter three times weekly (25,000 IU, 5 ml of 5,000 IU/ml).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Urokinase

Primary outcome measure
The main endpoints of the study were the occurrence of any Central Venous Catheter (CVC)-related infection by CoNS. According to previously described criteria these infections were classified as local CVC related infection (insertion site infection or significant CVC colonisation) and systemic CVC-related infections.

Secondary outcome measures
Secondary endpoints in this study were:
1. CVC-related infections caused by other microbial pathogens
2. Premature CVC removal
3. Secondary CVC-related complications (metastatic infection, CVC-related thrombosis)
4. Non-CVC related septicaemia bleeding
5. Death

Overall study start date
01/01/1996

Completion date
01/02/1999

Eligibility

Key inclusion criteria
1. Age of 18 years or older
2. Admission to undergo intensive cytotoxic treatment associated with disruption of the mucosa and deep granulocytopenia (Polymorphonuclear cells [PMNs] less than 0.1 x 10^9/L) for at least 14 days

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
161

Key exclusion criteria
1. Patients with pre-existing bleeding disorders
2. Patients treated with intravenous unfractionated heparin to prevent veno-occlusive disease
3. Patients with documented septicaemia prior to the start of the study

Date of first enrolment
01/01/1996

Date of final enrolment
01/02/1999

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre (LUMC)
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (The Netherlands)

Sponsor details
Department of Haematology
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
Hospital/treatment centre

Website
http://www.lumc.nl/english/start_english.html

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leiden University Medical Centre (LUMC) (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

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	20/01/2008		Yes	No