

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

Prospectively registered

Protocol

Registration date
07/03/2007

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
21/01/2008

Condition category
Infections and Infestations

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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Contact details

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Additional identifiers

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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 $0.1 \times 10^9/L$) for at least 14 days

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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)

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leiden University Medical Centre (LUMC) (The Netherlands)

Results and Publications

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