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Prevention of catheter-related deep vein thrombosis with nadroparin in hemato-oncology patients treated with high-dose chemotherapy

Submission date
09/06/2006

Recruitment status
No longer recruiting

Registration date
09/06/2006

Overall study status
Completed

Last Edited
08/01/2021

Condition category
Circulatory System

[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL611, NTR669

Study information

Scientific Title
Prevention of catheter-related deep vein thrombosis with nadroparin in hemato-oncology patients treated with high-dose chemotherapy

Study objectives
Low dose nadroparin will prevent symptomatic and asymptomatic catheter-related deep vein thrombosis in patients treated with high dose chemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomized controlled 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
Hemato-oncology patients with deep vein thrombosis

Interventions
Subcutaneous (SC) nadroparin 1 dd 2850 E versus subcutaneous placebo 0.3 ml for 21 days

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Nadroparin

Primary outcome measure
Asymptomatic and symptomatic catheter-related deep vein thrombosis proven by ultrasound or venography

Secondary outcome measures
1. Catheter-related infections
2. Bleeding complications

Overall study start date
10/04/2002

Completion date
01/07/2006

Eligibility

Key inclusion criteria
1. Central venous catheter
2. Indication for high dose chemotherapy (acute myeloid leukaemia [AML], acute lymphoblastic leukaemia [ALL], myelodysplasia-refractory anemia with excess of blasts in transformation [MDS-RAEB], multiple mye!oma [MM])
3. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Total final enrolment
113

Key exclusion criteria
1. Current anticoagulant therapy
2. Allergy for contrastmedia
3.Promyelocytic leukemia (AML-M3)
4. Bleeding tendency
5. Renal failure

Date of first enrolment
10/04/2002

Date of final enrolment
01/07/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

Sponsor details
P.O. Box 22660
Amsterdam
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Sponsor type
University/education

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
University/education

Funder Name
Academic Medical Center (AMC)

Alternative Name(s)
Academic Medical Center, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
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	01/09/2007	08/01/2021	Yes	No