

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	<input type="checkbox"/> Prospectively registered
Registration date 09/06/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/01/2021	Condition category Circulatory System	<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

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 myeloma [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 contrast media
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

Netherlands

1100 DD

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