

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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21969

Source

NTR

Brief title

N/A

Health condition

Clinical trial.

Sponsors and support

Primary sponsor: Academic Medical Center

Meibergdreef 9

1100 DD

Amsterdam

Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Asymptomatic and symptomatic catheter-related deep vein thrombosis proven by ultrasound or venography.

Secondary outcome

1. Catheter-related infections;
2. Bleeding complications.

Study description

Background summary

Double blind randomized controlled trial to analyze the efficacy of nadroparin on catheter-related deep vein thrombosis in patients treated with high chemotherapy.

Study objective

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

Study design

N/A

Intervention

Nadroparin SC 1 dd 2850 E versus placebo 0.3 ml SC during 21 days.

Contacts

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Eligibility criteria

Inclusion criteria

1. Central venous catheter;
2. Indication for high dose chemotherapy (AML, ALL, MDS-RAEB, MM);
3. Informed consent.

Exclusion criteria

1. Current anticoagulant therapy;
2. Allergy for contrastmedia;
3. AML-M3 (promyelocytic leukemia);
4. Bleeding tendency;
5. Renal failure.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2002
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion	
Date:	21-04-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL611
NTR-old	NTR669
Other	: N/A
ISRCTN	ISRCTN29686154

Study results

Summary results

J Thromb Haemost. 2007 Sep;5(9):1878-82.