Evaluation of the new guideline for diagnosis and treatment catheter-related thrombosis in neonates on the neonatal intensive care unit

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26109

Source
Nationaal Trial Register

Brief title
NeoClot

Health condition

Catheter-related thrombosis in neonates

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam
Source(s) of monetary or material Support: National working group neonatal catheter-related thrombosis

Intervention

Outcome measures

Primary outcome

Composite efficacy endpoint consists of incidence of recurrent VTE and death as result of VTE, after start of anticoagulant therapy + 3 days.
Primary safety endpoint is the frequency of major bleeding during anticoagulation treatment.

Secondary outcome

Secondary efficacy endpoints consists of the individual components of the primary efficacy endpoint.
Secondary safety endpoints are the frequency of clinically relevant non-major bleeding and minor bleeding occurring during anticoagulation treatment.

Additional endpoints are the frequency of risk factors for thrombosis, the frequency of protocol violations and the frequency of long-term consequences of thrombosis, i.e. post thrombotic syndrome and the presence of residual thrombosis.

Study description

Background summary

Observational study to investigate the efficacy and safety of a new national guideline for diagnosis and treatment of catheter-related thrombosis in neonates on the neonatal intensive care unit

Study objective

N/A

Study design

This observational study will last at least two years

Intervention

Patients will be treated according to the new guideline: Diagnosis and Treatment of catheter-related thrombosis in neonates

Contacts

Public

CH Ommen, van
ErasmusMC Sophia Children's Hospital
Rotterdam 3015CN
The Netherlands
010 7036691
Scientific
CH Ommen, van
ErasmusMC Sophia Children's Hospital
Rotterdam 3015CN
The Netherlands
010 7036691

Eligibility criteria

Inclusion criteria

All neonates and infants from 0 to 6 months of age on the neonatal intensive care unit with a catheter-related venous thrombosis

Exclusion criteria

No oral or written informed consent of the parents

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-01-2014
Enrollment:	100
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL4186
NTR-old	NTR4336
Other	: WPTS study 1-NeoClot
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A