TropicALL study

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23171

Source
Nationaal Trial Register

Brief title
DCOG TropicALL study

Health condition

TropicALL, ALL, Acute Lymphoblastic Leukemia, Thromboprophylaxis, Children Low-molecur-weight heparin, venous thrombosis.

TropicALL, ALL, Acute Lymfoblastische Leukemie, tromboprofylaxe, kinderen, laag-moleculair-gewicht heparine (LMWH), veneuze trombose

Sponsors and support

Primary sponsor: Dutch Childhood Oncology Group (DCOG)

Stichting Kinderoncologie Nederland (SKION)
Source(s) of monetary or material Support: The study will be financed by ZonMW 80-83600-98-10186

Intervention

Outcome measures

Primary outcome

Incidence of symptomatic objectified VTE during childhood ALL treatment in the intervention and standard arm.

Secondary outcome

1. Incidence of the composite of major bleeding or clinically relevant non-major bleeding in the intervention and standard arm;

2. Incidence of composite of asymptomatic and symptomatic objectified VTE during childhood ALL treatment in the intervention and standard arm.

3. ALL treatment outcomes by assessment of complete remission and (overall or disease-free) survival rates in the intervention and standard arm;

4. Identification of clinical risk factors and hematological biomarkers in consecutively included patients with and without VTE; to increase insight in the pathogenesis of coagulation disorders during ALL treatment, and to establish a risk model for VTE

Study description

Background summary

Not applicable

Study objective

Primary objective:

To assess the efficacy of thromboprophylaxis with high prophylactic dose LMWH as compared with standard care without systemic thromboprophylaxis in children treated for primary ALL.

Secondary objectives:

1. To assess the safety of thromboprophylaxis using high prophylactic dose LMWH as compared with standard of care without systemic thromboprophylaxis in children treated for newly diagnosed ALL, by assessment of the incidence of the composite of major bleeding or clinically relevant non-major bleeding

2. To assess whether ALL treatment with thromboprophylaxis using high prophylactic dose LMWH as compared with standard of care without systemic thromboprophylaxis influences complete remission and (overall or disease-free) survival rates of childhood ALL

3. To identify clinical risk factors or hematological biomarkers in ALL patients with and without symptomatic objectified VTE; to increase insight in the pathogenesis of coagulation

disorders during ALL treatment and to establish a risk model for VTE.

Study design

Eligibility for the TropicALL study will be evaluated directly after study inclusion in the ALL-11 or 12 study. In ALL-11, inclusion in the TropicALL study will take place within the first week of ALL treatment (day 11 at the latest), and after receiving written informed consent. Randomization will take place on day 11, the day before the first PEG-asparaginase administration (day 12). Randomization of each patient will be performed by a GCP proof randomization computer program at the DCOG trial office.

Non-continuous asparaginase schedule

Induction

- start: day 12 of Induction IA;

• continued until: day 54 (in total 43 days)
in Induction IA;

(until 14 days after the last PEG-asparaginase administration or 7 days after the last Erwinia asparaginase administration)

Medium Risk Intensification

• restart: in week 1 (on day of first asparaginase administration);

• continued until: week 29

continuous asparaginase schedule

Induction, Protocol M and Medium Risk intensification

• start: day 12 of Induction IA;

• continued until week 17 of MR intensification

Intervention

In the intervention arm, high prophylactic dose LMWH (nadroparin) is subcutaneously injected daily, adjusted to actual body weight with 85 IU anti-Xa/kg with a maximum of 5700 IU anti-Xa daily. Target anti-Xa level: 0.3-0.4 IU/ml)

Contacts

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Eligibility criteria

Inclusion criteria

All patients between 1 and 19 years of age with primary ALL, who are eligible for and treated within the DCOG ALL-11 or 12 study protocol.

Exclusion criteria

a. Patients who are already being treated with anticoagulation upon screening (for other indications)

b. Patients with a heparin allergy (or for one of its components), a recent history (within 6 months) of heparin-induced thrombocytopenia (HIT) or any other contraindication listed in the local labeling of LMWH

c. Patients without informed consent

d. Patients with active bleeding or high risk for bleeding contraindicating anticoagulant therapy (Thrombocytopenia is not an exclusion criterion)

e. Patients with renal insufficiency (glomerular filtration rate (GFR) < 30 ml/min/1.73m2)

f. Patients with hepatic disease which is associated with coagulopathy leading to a clinically

relevant bleeding risk

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-10-2014
Enrollment:	354
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	30-07-2014
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	NL4351
NTR-old	NTR4707
Other	EudraCT : 2014-003303-30

Study results