TropicALL study

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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...

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23171

Bron
Nationaal Trial Register

Verkorte titel
DCOG TropicALL study

Aandoening

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

Ondersteuning

Primaire sponsor: Dutch Childhood Oncology Group (DCOG)

Stichting Kinderoncologie Nederland (SKION)
Overige ondersteuning: The study will be financed by ZonMW 80-83600-98-10186

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

Not applicable

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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)

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-10-2014
Aantal proefpersonen:	354
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	30-07-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4351
NTR-old	NTR4707
Ander register	EudraCT : 2014-003303-30

Resultaten