INTERFANT-06.
International collaborative treatment protocol for infants under one year of age
with acute lymphoblastic or biphenotypic leukemia.

Gepubliceerd: 29-05-2006 Laatst bijgewerkt: 13-12-2022

The primary aim of the study is: 1. To assess the role of an early intensification of two "AML" induction blocks versus protocol Ib directly after induction, in a randomized way in MR and HR patients. Secondary aims are: 2. To assess...

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

Samenvatting

ID

NL-OMON20078

Bron
NTR

Verkorte titel
Interfant-06.

Ondersteuning

Primaire sponsor: the different international study groups
Overige ondersteuning: no

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Event free survival.

Toelichting onderzoek

Achtergrond van het onderzoek

Infant acute lymphoblastic leukemia (ALL) has a poor prognosis compared to ALL in older children. Becuase it is a rare disease, in 1999 an international collaboration was started to try to improve outcome for infant ALL. Interfant-99 was the first study leading to an event-free survival of 47%. Early bone marrow relapses were the major reason for therapy failure. The interfant-06 study aims to improve therapy by comparing two different early therapy intensifications: two "AML" induction blocks versus protocol Ib given directly after induction therapy in patients with a MLL gene rearrangement. Other aims are:
- to assess the outcome of the Interfant-06 protocol compared to the historical control series, especially the Interfant-99.
- To study which factors have independent prognostic value.
- To assess the role of SCT in patients at high risk for relapse.

Doel van het onderzoek

The primary aim of the study is:
1. To assess the role of an early intensification of two "AML" induction blocks versus protocol Ib directly after induction, in a randomized way in MR and HR patients.
Secondary aims are:
2. To assess the role of an early intensification of two "AML" induction blocks versus protocol Ib directly after induction, in a randomized way in MR and HR patients, separately.
3. To assess the overall outcome of the Interfant-06 protocol compared to the historical control series, especially the Interfant-99.
4. To assess the outcome of LR, MR and HR patients as compared to the historical control series in Interfant-99.
5. To study which factors have independent prognostic value.
6. To assess the role of SCT in HR patients.

Onderzoeksproduct en/of interventie

Comparison of early intensification of two "AML" induction blocks versus protocol Ib directly after induction, in a randomized way in medium risk and high risk patients.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Children aged 365 days or less with newly diagnosed acute lymphoblastic leukemia (ALL) or biphenotypic leukemia according to EGIL criteria. Children with CNS or testicular leukemia at diagnosis are eligible;
2. Morphological verification of the diagnosis, confirmed with cytochemistry and immunophenotyping. In case a bone marrow aspiration results in a “dry tap”, a trephine biopsy is advised unless it is possible to confirm the diagnosis by peripheral blood examination;
3. Informed consent of the parents or other legally authorized guardian of the patient.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Mature B-ALL, defined by the immunophenotypical presence of surface immunoglobulines or t(8;14) and breakpoint as in B-ALL;
2. The presence of the t(9;22) (q34;q11) or bcr-abl fusion in the leukemic cells (if these data are not known, the patient is eligible);
3. Age > 365 days;
4. Relapsed ALL;
5. Systemic use of corticosteroids less than 4 weeks before diagnosis. Patients who received corticosteroids by aerosol are eligible for the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2006
Aantal proefpersonen:	445
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-05-2006
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	NL635
NTR-old	NTR695
Ander register	: N/A
ISRCTN	ISRCTN12500962

Resultaten

Samenvatting resultaten
N/A