Comparative pharmacokinetics, pharmacodynamics, efficacy and safety of two asparaginase preparations in children with previously untreated acute lymphoblastic leukemia (ALL).

No registrations found.

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

Summary

ID

NL-OMON24878

Source
NTR

Brief title
N/A

Sponsors and support

Primary sponsor: Medac Research

Intervention

Outcome measures

Primary outcome

To determine the ratio of the population geometric means of the 72 hour serum concentration versus time curves (AUC) for the first administration of recombinant asparaginase versus Asparaginase medac.

Secondary outcome

1. Trough levels of ASNase activity in serum during subsequent ASNase infusions;

2. Serum and CSF levels of asparagine, aspartic acid, glutamine, glutamic acid;

3. CR rate and MRD status at day 33;

4. Adverse events.

Study description

Background summary

Children with newly diagnosed ALL receive either recombinant asparaginase or regular asparaginase during induction therapy (8 doses). Single centre, randomised, double-blind, parallel-group, phase II study. Aim is to compare pharmacokinetics, pharmacodynamics, efficacy and safety.

Study objective

Comparison of pharmacokinetics, pharmacodynamics, efficacy and safety of recombinant asparaginase(ASNase) versus Asparaginase medac during induction treatment in children with de novo ALL and to demonstrate that any clinical important difference to the disadvantage of recombinant ASNase is unlikely.

Study design

N/A

Intervention

Recombinant ASNase instead of regular ASNase Medac during induction therapy.

Contacts

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Eligibility criteria

Inclusion criteria

1. Previously untreated ALL;

2. Moprhological proof of ALL; bone marrow > 25%blasts;

3. Age 1-18 years;

4. Informed consent.

Exclusion criteria

1. Known allergy to ASNase;

2. General health status according to Karnofsky/Lansky <40%;

3. Pre-existing coagulopathy (e.g. hemophilia);

4. Pre-existing pancreatitis;

5. Kidney insufficiency (creatinine > 220 umol/L);

6. Liver insufficiency (bilirubin > 50 umol/L; ASAT and ALAT >5x upper limit of normal;

7. Other current malignancies;

8. Pregnancy, breast feeding;

9. Patients suffering from mental disorders.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2004
Enrollment:	32
Type:	Actual

Ethics review

Positive opinion

Date:	13-09-2005
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	NL363
NTR-old	NTR402
Other	: N/A
ISRCTN	ISRCTN75734403

Study results

Summary results
N/A