

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

Gepubliceerd: 13-09-2005 Laatste bijgewerkt: 18-08-2022

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 clinically important difference to...

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestopt       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON24878

### Bron

NTR

### Verkorte titel

N/A

### Ondersteuning

**Primaire sponsor:** Medac Research

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

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.

## Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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 clinically important difference to the disadvantage of recombinant ASNase is unlikely.

### Onderzoeksopzet

N/A

### Onderzoeksproduct en/of interventie

Recombinant ASNase instead of regular ASNase Medac during induction therapy.

## Contactpersonen

### Publiek

Erasmus Medical Center, Sophia Children's Hospital, Department of Oncology/Hematology,  
P.O. Box 2060  
Rob Pieters  
Dr. Molewaterplein 60

Rotterdam 3015 GJ  
The Netherlands  
+31 (0)10 4636691

## Wetenschappelijk

Erasmus Medical Center, Sophia Children's Hospital, Department of Oncology/Hematology,  
P.O. Box 2060  
Rob Pieters  
Dr. Molewaterplein 60

Rotterdam 3015 GJ  
The Netherlands  
+31 (0)10 4636691

## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Previously untreated ALL;
2. Morphological proof of ALL; bone marrow > 25% blasts;
3. Age 1-18 years;
4. Informed consent.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known allergy to ASNa;
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  $\mu\text{mol/L}$ );
6. Liver insufficiency (bilirubin > 50  $\mu\text{mol/L}$ ; ASAT and ALAT >5x upper limit of normal);
7. Other current malignancies;
8. Pregnancy, breast feeding;

9. Patients suffering from mental disorders.

## Onderzoeksopzet

### Opzet

|                  |                       |
|------------------|-----------------------|
| Type:            | Interventie onderzoek |
| Onderzoeksmodel: | Parallel              |
| Toewijzing:      | Gerandomiseerd        |
| Blinding:        | Dubbelblind           |
| Controle:        | Geneesmiddel          |

### Deelname

|                         |                       |
|-------------------------|-----------------------|
| Nederland               |                       |
| Status:                 | Werving gestopt       |
| (Verwachte) startdatum: | 01-11-2004            |
| Aantal proefpersonen:   | 32                    |
| Type:                   | Werkelijke startdatum |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 13-09-2005       |
| 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        | NL363          |
| NTR-old        | NTR402         |
| Ander register | : N/A          |
| ISRCTN         | ISRCTN75734403 |

## Resultaten

### Samenvatting resultaten

N/A