

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

<b>Submission date</b> 27/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/10/2008	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

NTR402

## **Study information**

**Scientific Title**

### **Study objectives**

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

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from the local medical ethics committee

### **Study design**

Single centre, randomised, double-blind, parallel-group, phase II study

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Acute lymphoblastic leukaemia (ALL)

### **Interventions**

Recombinant ASNase instead of regular ASNase Medac during induction therapy.

### **Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Recombinant asparaginase

**Primary outcome measure**

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 measures**

1. Trough levels of ASNase activity in serum during subsequent ASNase infusions
2. Serum and cerebrospinal fluid (CSF) levels of asparagine, aspartic acid, glutamine, glutamic acid
3. Complete remission (CR) rate and minimal residual disease (MRD) status at day 33
4. Adverse events

**Overall study start date**

01/11/2004

**Completion date**

01/11/2006

**Eligibility****Key inclusion criteria**

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

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

1 Years

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

32

## Key exclusion criteria

1. Known allergy to ASNase
2. General health status according to Karnofsky/Lansky less than 40%
3. Pre-existing coagulopathy (e.g. haemophilia)
4. Pre-existing pancreatitis
5. Kidney insufficiency (creatinine greater than 220 umol/l)
6. Liver insufficiency (bilirubin greater than 50 umol/l; aspartate aminotransferase [ASAT] and alanine aminotransferase [ALAT] greater than 5 x upper limit of normal)
7. Other current malignancies
8. Pregnancy, breast feeding
9. Patients suffering from mental disorders

## Date of first enrolment

01/11/2004

## Date of final enrolment

01/11/2006

## Locations

### Countries of recruitment

Netherlands

### Study participating centre

Erasmus MC-Sophia Children's Hospital Rotterdam  
Rotterdam  
Netherlands  
3015 GJ

## Sponsor information

### Organisation

Medac GmbH (Germany)

### Sponsor details

Theaterstrasse 6  
Wedel  
Germany  
D-22880

### Sponsor type

Industry

### ROR

<https://ror.org/05e0gzh77>

## Funder(s)

### Funder type

Not defined

### Funder Name

Not provided at time of registration

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	15/12/2008		Yes	No