ISRCTN75734403 https://doi.org/10.1186/ISRCTN75734403

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

Submission date 27/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 27/01/2006	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 07/10/2008	**Condition category** Cancer	[_] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 years

Upper age limit
18 years

Sex
All

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
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Sponsor information

Organisation
Medac GmbH (Germany)

ROR
https://ror.org/05e0gzh77

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

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?
Results article	Results	15/12/2008		Yes	No