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Comparison of anti-thymocyte globulin preparations in severe aplastic anaemia

Submission date
11/03/2010

Registration date
07/04/2010

Last Edited
07/04/2010

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
12

Study information

Scientific Title
Direct randomised comparison of horse anti-thymocyte globulin and rabbit anti-thymocyte globulin in children with severe aplastic anaemia

Study objectives

Rabbit anti-thymocyte globulin (ATG) has equivalent activity compared to standard horse ATG as part of combined immune suppression in children with severe aplastic anaemia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee of Research Institute of Pediatric Hematology approved on the 11th December 2000 (ref: 1-12-1999)

Primary study design
Interventional

Study design
Randomised two-period cross-over study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe aplastic anaemia

Interventions
Combined immunosupressive therapy with cyclosporin A and either horse ATG (ATGAM, Apjohn) - standard arm or rabbit ATG (ATG-Fresenius, Fresenius) - study arm.

Horse ATG (ATGAM) was used in a standard 160 mg\kg total dose, given as four consequtive daily 40 mg\kg doses as long I.V. infusion. Rabbit ATG (ATG-Fresenius) was given 40 mg\kg total dose, given as four consequtive daily 10 mg\kg doses as long I.V. infusion. Cyclosporine A was given per os in a 5 mg\kg\day for at least 18 months total duration. Total duration of follow up is 7 years.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Rabbit anti-thymocyte globulin (ATG), horse ATG

Primary outcome(s)
1. Minimal haematologic response rate at day 180 from therapy start
2. Complete haematologic response rate, assessed at last follow-up (5 years from time of enrolment of the last patient)
3. Overall survival, assessed at last follow-up (5 years from time of enrolment of the last patient)

Key secondary outcome(s)
1. Relapse probability in patients who achieved haematologic response, assessed at last follow-up (5 years from time of enrolment of the last patient)
2. Event-free survival, assessed at last follow-up (5 years from time of enrolment of the last

patient)
3. Toxicity, assessed at day 30 from therapy start

Completion date
01/02/2003

Eligibility

Key inclusion criteria
1. Aged from 1 - 18 years, either sex
2. Diagnosis of severe aquiered aplastic anaemia

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. Previous immune supressive therapy with ATG and/or cyclosporin A
2. Previous corticosteroid therapy over 2 weeks
3. Inherited bone marrow failure syndrome
4. Uncontrolled invasive fungal infection

Date of first enrolment
01/12/2000

Date of final enrolment
01/02/2003

Locations

Countries of recruitment
Russian Federation

Study participating centre

Leninskii prt 117
Moscow
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117997

Sponsor information

Organisation
Federal Clinical Research Center of Pediatric Hematology, Oncology and Immunology (Russia)

ROR
https://ror.org/02h8dsx08

Funder(s)

Funder type
Research organisation

Funder Name
Federal Clinical Research Center of Pediatric Hematology, Oncology and Immunology (Russia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration