

Comparison of anti-thymocyte globulin preparations in severe aplastic anaemia

Submission date 11/03/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/04/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/04/2010	Condition category Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Alexei Maschan

Contact details
Leninskii prt 117
Moscow
Russian Federation
117997
+7 495 936 91 69
amaschan@mail.ru

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)

Study design

Randomised two-period cross-over study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Severe aplastic anaemia

Interventions

Combined immunosuppressive 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 consecutive daily 40 mg/kg doses as long I.V. infusion. Rabbit ATG (ATG-Fresenius) was given 40 mg/kg total dose, given as four consecutive 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 acquired 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 suppressive 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
Russian Federation
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