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Comparison of anti-thymocyte globulin preparations in severe aplastic anaemia

Submission date 11/03/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 07/04/2010	**Overall study status** Completed	
Last Edited 07/04/2010	**Condition category** Haematological Disorders	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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)

Secondary outcome measures
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

Overall study start date
01/12/2000

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

Age group
Child

Lower age limit
1 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
40

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
Russian Federation
117997

Sponsor information

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

Sponsor details
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Sponsor type
Research organisation

Website
http://www.niidg.ru

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

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