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Adoptive immunotherapy for adenovirus (AdV)-associated complications post transplantation

Submission date 22/02/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 31/03/2006	**Overall study status** Completed	
Last Edited 31/03/2006	**Condition category** Cancer	

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
N/A

Study information

Scientific Title

Acronym
GAP-Protocol

Study objectives
Allogeneic AdV-specific T lymphocytes (ASTL) can be generated and used therapeutically with a low risk of graft versus host disease (GVHD)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval not yet received as of 31/03/2006

Study design
Prospective, randomized, double-blind, placebo-controlled, phase III multicenter trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pediatric patients with ALL, AML, CML or MDS following hematopoietic stem cell transplantation

Interventions
1. Treatment group will receive ASTL as prophylaxis and cidofovir as intervention.
2. Control group will receive placebo as prophylaxis and cidofovir as intervention.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
To determine the treatment related mortality (TRM), this will come into effect if:
1. TRM exceeds 35%

2. Acute GVHD III/IV exceeds 25%
3. Chronic GVHD II exceeds 25%
4. Non-hematopoietic toxicity 3-5 (according to NCI CTEP reporting criteria) exceeds 40%

Secondary outcome measures
1. Acute and chronic GVHD assessed by standard clinical grading scheme
2. Early non-hematopoietic toxicity grade according to NCI CTEP common terminology criteria for adverse events
3. Frequency and duration of AdV reactivations

Overall study start date
01/07/2006

Completion date
01/07/2011

Eligibility

Key inclusion criteria
Pediatric patients, aged 2 to 18 years with:
1. Acute leukemias (ALL)
2. Acute myeloid leukemia (AML)
3. Chronic myeloid leukemia (CML)
4. Myelodysplastic syndromes (MDS)

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
306

Key exclusion criteria
1. Patients in relapse or progress of AML or ALL and blast crisis of CML at the time of randomization
2. All second transplants
3. AdV seronegative recipients with seronegative matched related donors (MRD)

4. Patients with severe non-hematopoietic organ toxicity grade 3-5 (according to the National Cancer Institute [NCI] and Cancer Therapy Evaluation Program [CTEP] reporting criteria) at the time of randomization

Date of first enrolment
01/07/2006

Date of final enrolment
01/07/2011

Locations

Countries of recruitment
Germany

Study participating centre
Department of General Pediatrics
Berlin
Germany
13353

Sponsor information

Organisation
Charité - University Medicine Berlin (Germany)

Sponsor details
Augustenburger Platz 1
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Sponsor type
University/education

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Research organisation

Funder Name
German Research Foundation (Deutsche Forschungsgemeinsschaft) (DFG)

Funder Name
Vo 774/4-1

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