

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

Submission date 22/02/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 31/03/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 31/03/2006	Condition category Cancer	<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

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Additional identifiers

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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%

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 Years

Upper age limit

18 Years

Sex

All

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)

ROR

<https://ror.org/001w7jn25>

Funder(s)

Funder type

Research organisation

Funder Name

German Research Foundation (Deutsche Forschungsgemeinschaft) (DFG)

Funder Name

Vo 774/4-1

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration