

A phase I/II study of vaccination against minor histocompatibility antigens HA1 or HA2 after allogeneic stem cell transplantation for advanced haematological malignancies

Submission date 16/10/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 20/11/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 20/11/2008	Condition category Cancer	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

3578 (MHH) 1179/01 (PEI)

Study information

Scientific Title

Acronym

HA1/HA2

Study objectives

Our aim is to demonstrate the feasibility, safety and efficacy of vaccination with mHag HA1 or HA2 peptides on day +120 after HLA-identical allogeneic haematopoietic stem cell transplantation (HSCT) with mHag disparate donor recipient pairs. We reason that vaccination with recipient mHag will boost the graft-versus-leukaemia effect of HSCT and thus lower the incidence of relapse in patients with high risk haematological malignancies.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. MHH Ethics committee received on 30th May 2007 (ref: 3578)
2. Paul-Ehrlich-Institute received on 12th February 2007 (ref: 1179/01)

Primary study design

Interventional

Study design

Phase I/II experimental non-randomised, historical control trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Haematological malignancies/leukaemic relapse

Interventions

All patients will receive immunisation with mHA1 or 2 peptides in HLA-A2 patients with donor-recipient disparities in mHA1 or 2.

Historical controls will be used for evaluation of a benefit for patients with HA1 disparities and advanced haematological malignancies.

Duration of intervention per patient/subject: 18 months after vaccination.

Intervention Type

Drug

Phase

Phase I/II

Drug/device/biological/vaccine name(s)

mHag HA1 or HA2 peptides

Primary outcome(s)

Toxicity of immunisation

Key secondary outcome(s)

Prevention of relapse of leukaemia

Completion date

31/10/2011

Eligibility

Key inclusion criteria

1. Advanced (high risk) leukaemia, after allogeneic haematopoietic stem cell transplantation (HSCT)
2. Disparity in HA1 or HA2 between donor and recipient
3. Informed consent
4. Aged 18 years or older, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Acute or chronic graft-versus-host disease (GvHD) after allo-HSCT prior to immunisation
2. No informed consent

Date of first enrolment

01/11/2008

Date of final enrolment

31/10/2011

Locations

Countries of recruitment

Germany

Study participating centre

Hannover Medical School
Hannover
Germany
30625

Sponsor information

Organisation

Hannover Medical School (Medizinischen Hochschule Hannover) (Germany)

ROR

<https://ror.org/00f2yqf98>

Funder(s)

Funder type

Government

Funder Name

German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany) - grant via Integriertes Forschungs und Behandlungszentrum MHH (IFB)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration