ISRCTN11974092 https://doi.org/10.1186/ISRCTN11974092

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
Prof Arnold Ganser

Contact details
Hannover Medical School
Department of Hematology, Hemostasis, Oncology and Stem Cell Transplantation
OE6860
Carl-Neuberg-Str. 1
Hannover
Germany
30625

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

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

Primary study design
Interventional

Secondary study design
Non 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
Haematological malignacies/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 measure
Toxicity of immunisation

Secondary outcome measures
Prevention of relapse of leukaemia

Overall study start date
01/11/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

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)

Sponsor details
Carl-Neuberg-Str. 1
Hannover
Germany
30625
info@mh-hannover.de

Sponsor type
Hospital/treatment centre

Website
http://www.mh-hannover.de/

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

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