

PRE-emptive therapy of acute Graft Versus Host Disease according to specific proteomic patterns after allogeneic haematopoietic stem cell transplantation

Submission date 27/06/2007	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 19/12/2007	Overall study status Completed	☐ Protocol
Last Edited 02/09/2008	Condition category Injury, Occupational Diseases, Poisoning	☐ Statistical analysis plan
		☐ Results
		☐ 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 Eva M. Mischak-Weissingger

Contact details
Hannover Medical School
Department of Haematology, Haemostasis, Oncology and Stem Cell Transplantation
Carl-Neuberg-Str. 1
Hannover
Germany
30625
+49 (0)511 532 9518
mischak-weissingger.eva@mh-hannover.de

Additional identifiers

Protocol serial number
497Ganser_Weissingger

Study information

Scientific Title

Acronym

PRE-GVHD

Study objectives

Reduction of both severity and/or incidence of acute graft versus host disease (aGvHD) greater than grade II in the pre-emptively treated population as compared to placebo treated group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The collection/analysis of residual material as used in this study has already been approved by the Ethics Committee of the Hannover Medical School in November 2002 and November 2005 (ref: 3097).

Primary study design

Interventional

Study design

Prospective, double-blinded randomised placebo-controlled multi-centre study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Graft versus host disease after allogeneic haematopoietic stem cell transplantation

Interventions

Experimental intervention:

Pre-emptive immunosuppressive treatment (daily 2 mg methylprednisone/kg body weight [BW]) immediately at occurrence of an aGvHD grade II-specific proteome pattern.

Control intervention:

Placebo immediately at occurrence of a positive aGvHD grade II-specific proteome pattern.

Duration of intervention per patient:

2 mg/kg/kg BW steroids for five days if no clinical symptoms occur (taper steroids according to taper protocol), or until severity increases (clinical symptoms of aGvHD grade II; increase of symptoms in severity after three days, no change for seven days, intermediate response for 14 days).

In case of clinical aGvHD (greater than grade II) unblinding is necessary: the placebo group will start standard treatment with 2 mg methylprednisone/kg BW, treatment group will be open for second line therapy (e.g. 2 mg methylprednisone/kg BW and Antithymocyte Globulin (ATG) or clinic specific second line therapy).

Experimental and/or control off label or on label in Germany: not applicable.

Follow-up per patient: 100 days after HSCT.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Methylprednisone

Primary outcome(s)

Occurrence of aGvHD (greater than grade II) in placebo versus treatment group, between time of randomisation and 100 days after HSCT.

Key secondary outcome(s)

1. Increased overall survival in treatment group (day +365)
2. Reduction of severity of aGvHD (day +120)

Scientific endpoints (measured at end of study: three years):

1. Differentiation of aGvHD grade II to IV according to polypeptide markers
2. Organ specific aGvHD pattern
3. Generation of proteomic patterns for steroid resistant GvHD (will be acquired during the study)
4. Normalisation of aGvHD proteome pattern in response to treatment

Completion date

31/12/2010

Eligibility**Key inclusion criteria**

1. All patients greater than 18 years after allogeneic haematopoietic stem cell transplantation (allo-HSCT)
2. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Severe infections at the time of aGvHD-pattern positivity
2. No informed consent

Date of first enrolment

01/01/2008

Date of final enrolment

31/12/2010

Locations**Countries of recruitment**

Germany

Study participating centre

Hannover Medical School

Hannover

Germany

30625

Sponsor information**Organisation**

Hannover Medical School (Germany)

ROR

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

Funder(s)**Funder type**

Government

Funder Name

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany) (ref: 497Gasnser_Weissinger)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration