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

<b>Submission date</b> 27/06/2007	Recruitment status  No longer recruiting	[X] Prospectively registered
		☐ Protocol
Registration date 19/12/2007	Overall study status Completed	Statistical analysis plan
		☐ Results
Last Edited	Condition category	Individual participant data
02/09/2008	Injury, Occupational Diseases, Poisoning	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-weissinger.eva@mh-hannover.de

## Additional identifiers

# Protocol serial number

497Ganser\_Weissinger

# 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).

#### Study design

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

#### Primary study design

Interventional

#### 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

Αll

### 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