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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

Registration date
19/12/2007

Overall study status
Completed

Last Edited
02/09/2008

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/01/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
580 screening, 260 elegible, 90 randomisation

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)

Sponsor details
c/o Prof. Dr. med. Arnold Ganser
Director

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Sponsor type
Hospital/treatment centre

Website
http://www.mh-hannover.de/index.php?id=2&L=1

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

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