Trial Description

Title

Tansfusion of granulocytes for patients with febrile neutropenia

Trial Acronym

GRANITE

URL of the trial

[---]*

Brief Summary in Lay Language

**The immunesystem of cancerpatients after recieving a high-dose chemotherapy or stemcelltransplantation is weak (phase of aplasia) and the patients predisposed for infectious diseases. Patients undergoing a long time of fever after such therapies can not only be treated with antibiotics and/or antimycotics.
In this clinical trial we look for compatible donors of specific immunecells (granulocytes), stimulate the donor to produce more of them, to transfer them afterwards to the patients, like a blooddonation.**

Brief Summary in Scientific Language

This trial is used to evaluate the relevance of granulocyte-transfusion for patience with neutropenic fever. Especially high risk patients after high-dose chemotherapy or stemcelltransplantation with longtime aplasia need more than antibiotics and/or antimycotics.

Organizational Data

- DRKS-ID: **DRKS00000218**
- Date of Registration in DRKS: **2011/05/04**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **10-103 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1111-9560**
- EudraCT-No.
(for studies acc. to Drug Law): **2009-010700-28**

- PEI-No.: **1453/01**
- Sponsor-ID: **Uni-Köln-478 (Prüfplancode)**

Health condition or Problem studied

- ICD10: **C92.0 - Acute myeloid leukaemia**
- ICD10: **C91.0 - Acute lymphoblastic leukaemia**
- ICD10: **C92.1 - Chronic myeloid leukaemia**
- ICD10: **C91.1 - Chronic lymphocytic leukaemia**
- ICD10: **D46.9 - Myelodysplastic syndrome, unspecified**
- ICD10: **D47.1 - Chronic myeloproliferative disease**
- ICD10: **C82 - Follicular [nodular] non-Hodgkin's lymphoma**
- ICD10: **C83 - Diffuse non-Hodgkin's lymphoma**
- ICD10: **C84.4 - Peripheral T-cell lymphoma**
- ICD10: **C90.0 - Multiple myeloma**
- ICD10: **C81.9 - Hodgkin's disease: Hodgkin's disease, unspecified**
- MedDRA: **10016288: febrile Neutropenie / Febrile neutropenia**

Interventions/Observational Groups

- Arm 1: **Intervention-group:**
  Transfusion of standardized apharesis-products of granulocytes on every other day/alternating days
  + standard-therapy (antibiotics/antimycotics)
- Arm 2: **Control-group: standard-therapy without transfusion of granulocytes**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **III**
-

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Purpose: **Other**

Assignment: **Parallel**

Phase: **III**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

**Measurement of temperature (auricularly or orally);
Interventiongroup: 1h before, at starting time and ending of the transfusion of granulocytes, 1h, 12h and 24h after the transfusion.
Controlgroup: 0h (equates to 1h before the transfusion in the interventiongroup), 12h and 24h
Endpoint: the normalisation of the temperature (measurement intraauricular or oral; <38°C) for 72h**

Secondary Outcome

**End of neutropenia (not as a consequence of transfusions);
Value of neutrophile granulocytes in a bloodsample > 500/µl on two following days in an upward trend**

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik I für Innere Medizin, Köln**
- University Medical Center **Klinik für Innere Medizin, Hannover**
- University Medical Center **Klinik für Pädiatrie, Hannover**

Recruitment

- Planned/Actual: **Planned**

Planned/Actual: **Planned**

- (Anticipated or Actual) Date of First Enrollment: **2014/10/01**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **1 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

valid informed consent, subscribed by patient or his/her attorney
One of the following diseases:
- C92.0- acute myeloid leukaemia,
- C91.0- acute lymphoblastic leukaemia,
- C92.1- chronic myeloid leukaemia,
- C91.1- chronic lymphatic leukaemia,
- D46.9 myelodysplastic syndrome, unspecified,
- D47.1 chronic myeloproliferative disease,
- C82.- follicular (nodular) non-Hodgkin's lymphoma
- C83.- diffuse non-Hodgkin's lymphoma
- C84.4 peripheral T-cell lymphoma
- C90.0- Multiple myeloma
- C81.9 Hodgkin's lymphoma
Karnofsky Performance Status > 20%
echocardiography: ejection-fraction > 40%
creatinine clearance > 60ml/min
Pulmonary function: oxygensaturation at least 80%
therapy-refractory fever above 38°C without response to standard-therapy for 96 hours

Exclusion criteria

symptomatic coronary heart disease
cardial insuffiency NYHA III or IV
lungdisease with dyspnoea WHO III or IV
oxygensaturation < 80%
severe therapy-refractory arterial hypertension
non-therapy-induced neutropenia (e.g. aplastic anemia)
active psychiatric disease
severe kidney-dysfunction (creatinine-clearance < 60 ml/min)
severe hepatic-dysfunction with bilirubin > 2 mg/dl
insufficient therapy of a thyroid-dysfunction (T3/T4 out of the reference range)
Pregnancy or lactation
Noncontrollable life-threatening bleeding
Intracerebrally process leading to an increase of intracranial pressure (bleeding,

infectious disease, tumour)
cerebral convulsions
Karnofsky Performance Status < 20%
participation in the clinical trial in the last 30 days
medical or psychic condition, which does nor allow the patient to participate in the clinical trial, neither subscribe an informed consent, according to a doctor's opinion

Addresses

- **Primary Sponsor**

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  50923 Köln
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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Kennedyallee 40
53175 Bonn
Germany

Telephone: **0228 - 885-1**
Fax: **0228 - 885-2777**
E-mail: **postmaster at dfg.de**
URL: **http://www.dfg.de/**

Status

- Recruitment Status: **Recruiting withdrawn before recruiting started**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*