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Allogeneic stem cell mobilisation

Submission date 25/11/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/03/2012	**Overall study status** Completed	
Last Edited 17/10/2017	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Stem cell mobilization is a process where drugs are used to cause the movement of stem cells so that they can be collected and used for a stem cell transplant. The drug ratiograstim has been approved for the mobilization of peripheral stem cells (from the bloodstream). The aim of this study is to assess the effectiveness and safety of peripheral stem cell mobilization by either ratiograstim or the reference drug G-CSF.

Who can participate?
Patients undergoing a stem cell transplant for hematological malignancies (cancers that affect the blood and lymph system) and their related healthy donors

What does the study involve?
Participating donors are treated with either ratiograstim or G-CSF and the effectiveness and safety of the two drugs is compared.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Universität Heidelberg (Germany)

When is the study starting and how long is it expected to run for?
January 2010 to November 2011

Who is funding the study?
Ratiopharm GmbH (Germany)

Who is the main contact?
Prof. Michael Schmitt

Contact information

Type(s)
Scientific

Contact name
Prof Michael Schmitt

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Additional identifiers

Protocol serial number
Rostock01

Study information

Scientific Title
Application of the granulocyte colony-stimulating factor (G-CSF) biosimilar ratiograstim for the mobilisation of peripheral stem cells in healthy donors

Study objectives
Effectivity of the biosimilar ratiograstim is similar to original G-CSF.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Federal Authority (Bundesamt für Arzneimittel, BfArM), 21/07/2010, ref: SNR: 250906/10

Primary study design
Interventional

Study design
Non-randomised trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Allogeneic stem cell transplantation

Interventions
Two cohorts, one cohort of 11 patients and donors receiving the biosimilar Ratiograstim® versus another cohort of 11 patients and donors receiving reference G-CSF. Results in this study arm were compared with results of a matched historical control

Intervention Type

Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Efficacy in peripheral stem cell mobilisation

Key secondary outcome(s)
Safety in peripheral stem cell mobilisation

Completion date
30/11/2011

Eligibility

Key inclusion criteria
1. Donors had no known allergy to G-CSF
2. Siblings (match-related donors)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Younger than 18 years

Date of first enrolment
01/01/2010

Date of final enrolment
30/11/2011

Locations

Countries of recruitment
Germany

Study participating centre

Universität Heidelberg
Heidelberg
Germany
69120

Sponsor information

Organisation
University of Heidelberg (Universität Heidelberg) (Germany)

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
Industry

Funder Name
Ratiopharm GmbH (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2013		Yes	No