

Allogeneic stem cell mobilisation

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| Submission date 25/11/2011 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 30/03/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 17/10/2017 | Condition category Surgery | <input type="checkbox"/> Individual participant data |

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

Contact details

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Germany
69120

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

Study design

Non-randomised trial

Primary study design

Interventional

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 |