

# Allogeneic stem cell mobilisation

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

Universität Heidelberg  
Hämatologie  
Grabengasse 1  
Heidelberg  
Germany  
69120

**Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please contact [mathias.freund@onkologie-rostock.de](mailto:mathias.freund@onkologie-rostock.de) to request a patient information sheet

**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 measure**

Efficacy in peripheral stem cell mobilisation

**Secondary outcome measures**

Safety in peripheral stem cell mobilisation

**Overall study start date**

01/01/2010

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

22

**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)

**Sponsor details**

c/o Prof. Dr. med. michael schmitt

Hämatologie

Grabengasse 1

Heidelberg

Germany

69117

**Sponsor type**

University/education

**ROR**

<https://ror.org/038t36y30>

**Funder(s)****Funder type**

Industry

**Funder Name**

Ratiopharm GmbH (Germany)

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2013		Yes	No