EPC quantification after G-CSF stimulation in healthy volunteers

Published: 30-08-2007
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Primary objective is:To determine whether a single subcutaneous injection of G-CSF induces an immediate (within six hours) release of bone marrow progenitor cells in healthy volunteers.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON31566

Source
ToetsingOnline

Brief title
G-CSF study

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer, malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: EPC, G-CSF, volunteer

Outcome measures

Primary outcome

Primary objective is:

To determine whether a single subcutaneous injection of G-CSF induces an

immediate (within six hours) release of bone marrow progenitor cells in healthy

volunteers.

Secondary outcome

nvt

Study description

Background summary

Recent findings have demonstrated that several chemotherapeutics induce an immediate release of bone marrow progenitor endothelial cells. This release occurs within hours after administering chemotherapy to the patient. The clinical relevance of the release of bone marrow derived cells is currently unclear. In preclinical tumor models perturbation of the tumor with a vascular disrupting agent induces a similar release which coincides with rapid regrowth of the tumor. In G-CSF receptor knock-out mice, this EPC burst didn*t occur, indicating that G-CSF might be the primary stimulus for this release of bone marrow derived endothelial cells.

Study objective

Primary objective is:
To determine whether a single subcutaneous injection of G-CSF induces an immediate (within six hours) release of bone marrow progenitor cells in healthy volunteers.

Study design

Healthy volunteers who are willing to participate and who signed informed

consent will be injected with a one time subcutaneous injection of filgrastim of 0.03 µg or saline 0.9% (1ml). Patients will undergo a venipuncture for sampling of approximately 13 ml of blood and in total there will be collected a volume of 62 ml blood at 4 different timepoints. Analysis of EPC/CEC dynamics will be performed by flowcytometry and analysis of G-CSF levels by ELISA procedures.

Intervention

Healthy volunteers who are willing to participate and who signed informed consent will be injected with a one time subcutaneous injection of filgrastim of 0.03 µg or saline 0.9% (1ml). Patients will undergo a venipuncture for sampling of approximately 9 ml of blood and in total there will be collected a volume of 45 ml blood. Analysis of EPC/CEC dynamics will be performed by flowcytometry and analysis of G-CSF levels by ELISA procedures.

Study burden and risks

Extent of burden for the volunteer is composed of the fact that he will undergo a venapuncture for a iv canule once and that he will be injected once subcutaneously with filgrastim, and the time he has to spent in the hospital, namely six hours. The risks are the development of a hemorrage after venapuncture.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1.The volunteer must be >= 18 years of age
2.The volunteer must be healthy
meaning having no relevant medical history and havind no clinical signs of intercurrent infection at physical exam at start of the study
3.The volunteer mustn*t have known hypersensitivity to the to be administrated drugs (filgrastim®)
4.The patient must have given written informed consent
5. women wild child bearing potential must have a negative serum pregnancy test 48 hrs before start

Exclusion criteria

Any other condition by which the patient doesn*t meet the inclusion criteria

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2007
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Neupogen
Generic name:	Filgrastim
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	30-08-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-10-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-03-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-06-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-004140-73-NL
CCMO	NL18948.041.07