Safety and efficacy of hLF1-11 for the treatment of infectious complications among haematopoietic stem cell transplant recipients.
Part B: Clinical Study Protocol SC13: Safety of a 5 mg dose of hLF1-11 given for 10 consecutive days to autologous haematopoietic stem cell transplant recipients

Published: 12-06-2007
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To establish the safety and tolerablity of multiple doses of hLF1-11 given once daily for 10 days.

Ethical review	Approved WMO
Status	Pending
Health condition type	Plasma cell neoplasms
Study type	Interventional

Summary

ID

NL-OMON31209

Source
ToetsingOnline

Brief title
Safety of hLF1-11 in autologous HSCTrecipients

Condition

- Plasma cell neoplasms

Synonym
infecti

Research involving
Human

Sponsors and support

Primary sponsor: AM-Pharma
Source(s) of monetary or material Support: AM Pharma

Intervention

Keyword: autologous HSCT, hLF1-11, safety

Outcome measures

Primary outcome

Safety and tolerability as measured by adverse events, laboratory

abnormalities, alterations in vital signs and the elaboration of specific

anti-hLF1-11 antibodies.

Secondary outcome

Not applicable

Study description

Background summary

hLF1-11 is an antimicrobial peptide comprising the first 11 amino acids found in the naturally occurring lactoferrin that plays a role in the innate host response against bacterial and fungal diseases. Animal infections models have shown hLF1-11 to be effective in treating infections due to bacteria such as Staphylococcus aureus and fungi such as Candida albicans and the drug has been shown to be well tolerated and safe in volunteers. Recipients of stem cell transplant are at risk of developing infectious complications due to invasive fungal or bacterial disease. These patients are different from healthy volunteers because they have received myeloablative treatment, which not only arrests haematopoiesis resulting in neutropenia but also induces mucosal barrier injury both of which predispose to infections. It is therefore

essential to know that hLF 1-11 is safe and well tolerated when given during neutropenia and mucosal barrier injury before infections ensue

Study objective

To establish the safety and tolerablity of multiple doses of hLF1-11 given once daily for 10 days.

Study design

Open label prospective study of the safety and tolerability of 5 mg hLF1-11 given once daily for 10 days to recipients of an autologous haematopoietic stem cell transplant.

Intervention

5 mg hLF1-11 given once daily for 10 consecutive days

Study burden and risks

Extra blood will be drawn through the central venous catheter

Contacts

Public
AM-Pharma

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

· has been admitted for an autologous HSCT after myeloablative therapy with high-dose melphalan;
· is being managed with a 3 or 4-lumen central venous catheter;
· is at least 18 years old;
· has a BMI < 30 kg/M2;
· has no medical reason for not participating;
· has adequate renal function (creatinine < 1.5 x ULN) ;
· has adequate liver function (ASAT, ALAT < 2.5 x ULN, bilirubin < 1.5 x ULN);
· if a woman, is functionally post-menopausal;
· has not participated in a study of a new chemical molecular entity in the previous 3 months;
· is able and willing to participate;
· has provided written informed consent.

Exclusion criteria

Not applicable

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2007
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Not available
Generic name:	human lactoferrin 1-11

Ethics review

Approved WMO Date:	03-08-2007
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-10-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2006-004012-52-NL
CCMO	NL16479.091.07