

Safety and efficacy of human lactoferrin hLF1-11 for the treatment of infectious complications among haematopoietic stem cell transplant recipients

Submission date 09/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/06/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/04/2010	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr B.Th.M. Bierman

Contact details
AM-Pharma B.V.
Rumpsterweg 6
Bunnik
Netherlands
3981 AK
+31 (0)30 2289222
B.Bierman@AM-Pharma.com

Additional identifiers

Study information

Scientific Title

Acronym

AMP 02-01

Study objectives

A peptide representing the first eleven residues of hLF (hLF1-11) was shown to be effective in killing a variety of bacteria in vivo. The objective is to develop hLF1-11 as an effective and safe antibacterial and antifungal for the treatment of infections that develop during the neutropenia resulting from myeloablative therapy to prepare for a haematopoietic stem cell transplant.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Non randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Neutropenic stem cell transplantation patients

Interventions

Study medication hLF1-11 of 5 mg will be given by intravenous administration. hLF 1-11 will be dissolved in sterile 0.9 % NaCl to a volume of 20 ml to be administered at 1 ml/min over 20 mins.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Lactoferrin

Primary outcome(s)

Safety and tolerability as measured by adverse events, local tolerability, clinical chemistry, haematology, and vital signs.

Key secondary outcome(s)

To evaluate formation of antibodies, anti-hLF 1-11 enzyme-linked immunosorbent assay (ELISA) will be measured during and after the study up to two weeks post dosage administration.

Completion date

31/05/2006

Eligibility

Key inclusion criteria

1. Admitted for an autologous hematopoietic stem cell transplantation (HSCT) after myeloablative therapy with high-dose melphalan
2. Managed with a 4-lumen central venous catheter
3. 18 to 45 years of age
4. Body mass index (BMI) <30
5. Able and willing to participate
6. Has provided written informed consent
7. There is no medical reason for exclusion
8. Has adequate renal function (creatinine <110 µmol/l [man]; <90 µmol/l [woman])
9. Has adequate liver function aspartate aminotransferase (ASAT) <40 U; alanine aminotransferase (ALAT) <45 U; bilirubin <10 µmol/l)
10. Has no known allergy to lactoferrin
11. Has no history of hepatitis and is not human immunodeficiency virus (HIV)-seropositive
12. If a woman, functionally post-menopausal

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. A history of, or presence of, significant respiratory, cardiovascular, neurological, haematological, endocrine, gastrointestinal, hepatic or renal disease or any other condition known to interfere with the absorption, distribution, metabolism or excretion of drugs (as judged clinically relevant by the investigator)
2. Participation in a study with a new chemical entity or new molecular entity 3 months before or participation in a study with a registered drug less than 5 times of the half life of the registered drug before entering the study
3. A clinically relevant history of intolerance or hypersensitivity to the study drug, or its additives and excipients in the intravenous formulation
4. Evidence of having serum hepatitis or carrying the hepatitis B surface antigen or hepatitis C antibodies or being HIV positive
5. Subjects, who in the opinion of the investigator should not, for reasons of safety, participate in the study

Date of first enrolment

06/03/2006

Date of final enrolment

31/05/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

AM-Pharma B.V.

Bunnik

Netherlands

3981 AK

Sponsor information

Organisation

AM-Pharma B.V. (Netherlands)

ROR

<https://ror.org/02bpbnv34>

Funder(s)

Funder type

Industry

Funder Name

SenterNovem (Netherlands)

Funder Name

AM-Pharma B.V. (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration