ISRCTN27226314 https://doi.org/10.1186/ISRCTN27226314

# 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

**Registration date**
09/06/2006

**Overall study status**
Completed

**Last Edited**
01/04/2010

**Condition category**
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
N/A

# 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

### Secondary study design
Non randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

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

### Secondary outcome measures
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.

### Overall study start date
06/03/2006

### 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 melfalan
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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
8

### 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)

### Sponsor details
Rumpsterweg 6
Bunnik
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3981 AK

**Sponsor type**
Industry

**ROR**
https://ror.org/02bpbnv34

# Funder(s)

**Funder type**
Industry

**Funder Name**
SenterNovem (Netherlands)

**Funder Name**
AM-Pharma B.V. (Netherlands)

# 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