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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
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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