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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20231

Bron
Nationaal Trial Register

Verkorte titel
AMP 02-01

Aandoening

Patients who have received myeloablative treatment resulting in neutropenia and mucosal barrier injury and are therefore susceptible to fungal and bacterial infections.

Ondersteuning

Primaire sponsor: AM-Pharma B.V
Rumpsterweg 6
3981 AK Bunnik
Tel +31 (0) 30 228 92 22
Fax +31 (0) 30 228 92 20

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

Open label prospective trial of a single 5 mg dose of hLF1-11 in autologous haematopoietic stem cell transplant (HSCT) recipients. Eight (8) subjects will receive a single intravenous dose of hLF1-11 given in a volume of 20 mL given over 20 min.
Adverse events whether infectious or non-infectious whether reported by the patient spontaneously or by the nursing and medical carers will be recorded according to World Wide Standards as will any abnormalities in clinical chemistry, haematology, urine analysis or vital signs (BP, heart rate and temperature).

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

AM-Pharma B.V.,
Rumpsterweg 6
B.Th.M. Bierman
Bunnik 3981 AK
The Netherlands
+31 (0)30 2289222

Wetenschappelijk

AM-Pharma B.V.,
Rumpsterweg 6
B.Th.M. Bierman
Bunnik 3981 AK
The Netherlands
+31 (0)30 2289222

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Admitted for an autologous 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. 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 (ASAT <40 U; ALAT <45 U; bilirubin <10µmol/L);

10. Has no known allergy to lactoferrin;

11. Has no history of hepatitis and is not HIV seropositive;

12. If a woman, functionally post-menopausal.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. A history of, or presence of, significant respiratory, cardiovascular, neurological, haematological, endocrine, gastro intestinal, hepatic or renal disease or 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestopt

(Verwachte) startdatum:	06-03-2006
Aantal proefpersonen:	8
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	21-04-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL613
NTR-old	NTR672
Ander register	: N/A
ISRCTN	ISRCTN27226314

Resultaten

Samenvatting resultaten
N/A