A phase-I, double-blind, randomized, controlled study on the tolerability and early efficacy of hLF1-11 in hospitalized patients with bacteremia due to Staphylococcus epidermidis.

Published: 07-08-2007
Last updated: 14-05-2024

To establish the safety, tolerability, and early efficacy of multiple doses of hLF1-11 given once daily for 10 days

Ethical review	Approved WMO
Status	Pending
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON31208

Source
ToetsingOnline

Brief title
not applicable

Condition

- Bacterial infectious disorders

Synonym
bacterial skin infection, Staphylococcus Epidermidis infection

Research involving
Human

Sponsors and support

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

Intervention

Keyword: hLF1-11, Infection, Lactoferrin, Staphylococcus

Outcome measures

Primary outcome

• To investigate the safety of hLF1-11 in patients with Staphylococcus

epidermidis-positive blood cultures.

Secondary outcome

• To obtain in vitro susceptibility data on staphylococcal infections from

patients participating in the study.

• To explore the relationship of drug exposure to cure rates (TOC) in

bacteriologically (blood culture) evaluable patients.

Study description

Background summary

Staphylococcus epidermidis is a relatively uncommon find in blood cultures, most cases being found in patients with intravenous lines through contiguous contamination and current clinical practice is often one of not using antibiotic treatment immediately, unless significant clinical signs and symptoms and/or patient status justifies intervention with an antibiotic. The latter tends to be vancomycin as many S epidermidis strains are resistant to other agents.

hLF1-11 is hypothesized to have antibacterial effects against Staphylococcus epidermidis, amongst other strains.
Should hLF1-11 be shown to be an effective antibacterial against Staphylococcus epidermidis, its use would be justified in other more serious hospital-acquired infections such as MRSA for which hLF1-11 has been shown (in preclinical in

vitro and in vivo data) to display a strong therapeutic effect.

Study objective

To establish the safety, tolerability, and early efficacy of multiple doses of hLF1-11 given once daily for 10 days

Study design

This phase-I, double-blind, randomized, controlled study is designed to study the tolerability and early efficacy of hLF1-11 in hospitalized patients with bacteremia due to Staphylococcus epidermidis.
Two groups of 10 patients (2 groups of n=10, N=20) will be included. One group will be treated with hLF1-11 and the other will receive matching placebo. Although S epidermidis is not routinely treated with antibiotics, all patients may also receive any antibiotic that becomes indicated after 96 hours from start of study medication.
All decisions on *tolerability* will be made by the Principal Investigator(s) in consultation with the Independent Data Safety Monitoring Committee (IDSMC) who will oversee all safety aspects of the study on an ongoing basis and will advise the PI(s) and Sponsor including on implementation of stopping rules under separate protocol (available upon request).

N=20 (2 groups of N=10)
Randomization ratio: 1:1

Intervention

0.5mg hLF1-11 given once daily for 10 consecutive days.

Study burden and risks

Extra blood will be drawn through the central venous catheter

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Hospitalized patients with positive blood culture for Staphylococcus epidermidis.
• Diagnosis of staphylococcal infection based on a positive culture for Staphylococcus epidermidis on 2 consecutive occasions within 12 hours.
• Study medication must be started not later than 24 hours of the last qualifying positive blood culture.
• Patients for whom antibiotic treatment is not clinically indicated at the start of the study.
• Patients must have sufficient venous access to permit administration of study drug and monitoring of safety variables.
• Patients who have hepatic and renal parameters within 2X ULN (upper level of normality) at screening.
• Fecund females patients must not be pregnant (confirmed by pregnancy test at entry) and must be on appropriate mechanical (intra-uterine device) or pharmacological (*pill*) contraception.
• Written informed consent must be obtained before admission in the study.

Exclusion criteria

• Prior antibiotic usage: patients who have received (within 48 hours of study entry) a systemic anti-staphylococcal antibiotic for longer than 24 hours.
• Concomitant antibiotic or anti-bacterial agents except as allowed by the protocol or in life-threatening complications.
• Patients with devices infected with Staphylococcus epidermidis or other important pathogens, including in implants, heart valves and catheters.

• Patients known to have AIDS or who are HIV-positive.
• Neutropenic patients with neutrophil count below 0.5x109/L.
• Patients with staphylococcal endocarditis, mediastinitis, meningitis, osteomyelitis and/or joint infections, lung/pleural infections, septic shock.
• Patients with methicillin-sensitive coagulase-negative staphylococcus (CNS) infections (MSSE).
• Patients who have known hypersensitivity to any constituent of hLF1-11.
• Patients who have received an investigational drug within three months prior to the study that may interfere with the interpretation of study results.
• Patients with a concomitant medical condition, in whom, in the opinion of the Investigator, participation may create an unacceptable risk for the patient.
• Patients considered inappropriate by the PI for enrolment in the study, for any reason.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	not applicable
Generic name:	human lactoferrin peptide

Ethics review

Approved WMO Date:	07-08-2007
Application type:	First submission
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	EUCTR2007-003869-40-NL
CCMO	NL18833.091.07