A Double-blind, Randomised, Placebo-controlled, Phase 2b/3 Adaptive Clinical Trial Investigating the Efficacy and Safety of Selepressin as Treatment for Patients with Vasopressor-dependent Septic Shock

Published: 20-07-2015
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To demonstrate superiority of selepressin plus standard care versus placebo plus standard care in the number of vasopressor- and mechanical ventilator-free days (with penalty for mortality) in patients with vasopressor-dependent septic shock

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Decreased and nonspecific blood pressure disorders and shock
Study type	Interventional

Summary

ID

NL-OMON43990

Source
ToetsingOnline

Brief title
Ferring 000133 SEPSIS-ACT

Condition

- Decreased and nonspecific blood pressure disorders and shock

Synonym
shock, Vasopressor-dependent septic shock

Research involving

Human

Sponsors and support

Primary sponsor: Ferring
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Selepressin, Vasopressor-dependent Septic Shock

Outcome measures

Primary outcome

Vasopressor- and mechanical ventilator-free days (P&VFDs) up to Day 30. This composite endpoint is defined as the number of days (reported to one decimal place [0.0 to 30.0 days]) from start of treatment with the investigational medicinal product (IMP) [selepressin or placebo] to 30.0 days thereafter during which the patient is: 1) alive; 2) free of treatment with intravenous vasopressors; and 3) free of any invasive mechanical ventilation.

Secondary outcome

All-cause mortality (defined as the fraction of patients that have died, regardless of cause) at Day 90

Renal replacement therapy (RRT)-free days up to Day 30 (excluding patients on RRT for chronic renal failure at time of randomisation)

Intensive care unit (ICU)-free days up to Day 30

Study description

Background summary

Selepressin may serve a dual role of providing haemodynamic benefit while reducing the leakage of intravascular fluid into the extracellular space. It is believed that these unique characteristics could help address the unmet need in the treatment of vasopressor-dependent septic shock and provide significant benefit for the patients.

Study objective

To demonstrate superiority of selepressin plus standard care versus placebo plus standard care in the number of vasopressor- and mechanical ventilator-free days (with penalty for mortality) in patients with vasopressor-dependent septic shock

Study design

This is a double-blind, randomised, placebo-controlled, two-part adaptive clinical trial. The trial is designed to investigate the efficacy and safety of multiple dosing regimens of selepressin and to confirm the efficacy and safety of one dosing regimen in treatment of adult patients with septic shock requiring vasopressor.

Intervention

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Study burden and risks

Risk of participating in the trial
Selepressin is an investigational drug and problems or adverse events that are not known at this time may occur. It is possible that selepressin could cause reactions or discomfort and there may be risks to patients participating in this trial. The potential risks associated with the participation in this research trial will be explained to the subject (or the legally authorised representative) before the decision to participate or not. The trial staff will follow the subject*s condition closely from the onset of septic shock and look for and treat any possible adverse events.

It is not known whether selepressin will harm an unborn baby. Therefore, pregnant women cannot participate in the trial.

Benefit of participating in the trial
The subject may benefit as a result of his/her participation in this trial. However, there is no guarantee that the subject will benefit from the participation in this trial.

The information obtained from this trial may help the trial doctor and other doctors to better treat patients with septic shock in the future.

Contacts

Public
Ferring

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. 18 years of age or older.
2. Proven or suspected infection.
3. Septic shock defined as hypotension (systolic blood pressure less than 90 mmHg OR MAP less than 65 mmHg) requiring vasopressor treatment (i.e. any dose of norepinephrine / noradrenaline greater than 5 *g/min) despite adequate fluid resuscitation (at least one litre for hypotension).
4. Informed consent obtained in accordance with local regulations.

Exclusion criteria

1. Not possible to initiate IMP treatment within 12 hours from onset of vasopressor treatment for septic shock.
2. Primary cause of hypotension not due to sepsis (e.g. major trauma including traumatic brain injury, haemorrhage, burns, or congestive heart failure/cardiogenic shock).
3. Previous severe sepsis with ICU admission within this hospital stay.
4. Known/suspected acute mesenteric ischaemia.
5. Suspicion of concomitant acute coronary syndrome based on clinical symptoms and/or ECG during this episode of septic shock.
6. Chronic mechanical ventilation for any reason OR severe chronic obstructive pulmonary disease (COPD) requiring either continuous daily oxygen use during the preceding 30 days or mechanical ventilation (for acute exacerbation of COPD) during the preceding 30 days.
7. Received bone marrow transplant during the preceding 6 months or chemotherapy during the preceding 30 days for lymphoma or leukemia.
8. Known to be pregnant.
9. Decision to limit full care taken before obtaining informed consent.
10. Use of vasopressin in the past 12 hours prior to start of the IMP infusion or use of terlipressin within 7 days prior to start of the IMP infusion.
11. Prior enrolment in the trial.
12. Prior use of an investigational medicinal product within the last month OR planned or concurrent participation in a clinical trial for any investigational drug or investigational device.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	25-10-2016
Enrollment:	225
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Selepressin
Generic name:	Selepressin

Ethics review

Approved WMO Date:	20-07-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-01-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-05-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-06-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-08-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-09-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	11-09-2017
Application type:	Amendment
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	EUCTR2014□003973□41-NL
ClinicalTrials.gov	NCT02508649
CCMO	NL53983.091.15