Safety and Performance Evaluation of Seraph 100 Microbind Affinity Blood Filter (Seraph 100) in the reduction of pathogen load from the blood in septic patients with suspected, life-threatening bloodstream infection.

Published: 22-04-2020
Last updated: 08-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49017

Source
ToetsingOnline

Brief title
CP015

Condition

- Other condition
- Immune disorders NEC
- Hepatobiliary neoplasms malignant and unspecified

Synonym
Sepsis;

Health condition

Sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Exthera Medical Europe B.V.
Source(s) of monetary or material Support: door de sponsor;ExThera Medical Europe BV

Intervention

Keyword: bloodstream infection, Sepsis

Outcome measures

Primary outcome

Reduction of pathogens load from the bloodstream during treatment

Time frame: [(4,5 hours ± 30 min)]

Secondary outcome

All-cause mortality

Time frame: [90 Days]

• Persistence/Recurrence of bacteremia

Time frame: [Day 1, Day 2, Day 7]

• Persistence/Recurrence of sepsis

Time frame: [Daily during ICU stay or at least Day 1, Day 2, Day7]

Organ dysfunction-free days

Time frame: [Daily during ICU stay or at least Day 1, Day 2, Day 7]

• Reduction of Intensive Care Unit (ICU) complications

Time frame: [Daily during ICU stay]

• Ventilator-free days (VFDs)

Time frame: [Daily during ICU stay or at least Day 1, Day 2, Day 7]

• Length of stay (LOS) at ICU and hospital ward

Safety endpoint

N (%) of patients with treatment emergent adverse events

Study description

Background summary

Seraph 100 Microbind Affinity Blood Filter is used to reduce pathogen load during bloodstream infection. Bacteremia or bloodstream infection, also called BSI, occurs when a bacterial infection elsewhere in the body enters the bloodstream. This clinical condition can quickly become life-threatening and progress to sepsis. Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection (Singer et al., 2016).When sepsis occurs with extremely low blood pressure, it*s called septic shock. Septic shock is fatal in many cases.
Sepsis can be triggered by many types of bacteremia although the exact source of the infection often cannot be determined. Some of the most common infections that lead to BSI are lung infections (i.e. pneumonia) and infections in the abdominal area. Patients who are already in the hospital for something else, such as a surgery, are at a higher risk of developing BSI. These infections are even more dangerous when the bacteria are already resistant to antibiotics. The National Institutes of Health (NIH) estimates that over 1 million Americans get sepsis each year. Between 28 and 50 percent of these patients may die from the condition.

Study objective

The primary objectives are to demonstrate the safety and performance of the Exthera Medical Seraph 100 Microbind Affinity Blood Filter in the reduction of pathogen load from the blood in septic patients with suspected, life-threatening bloodstream infection (BSI).

Study design

This is a prospective, open-label, randomized, controlled clinical

investigation designed to evaluate the safety and performance of Exthera Medical Seraph 100 Microbind Affinity Blood Filter in the reduction of pathogen load from the blood in septic patients with suspected, life-threatening bloodstream infection (BSI).
The clinical investigation will be conducted at approximately 16 centers in Europe. Subjects will be randomized to the treatment group (Seraph 100 + antibiotic therapy) versus control group (antibiotic therapy only).
Subjects will be followed until the last subject completes their 3-months follow-up phone call. Clinical Investigation follow-up will occur at Baseline (confirmation of eligibility), Day 0 or Treatment, Follow-up visits at Day 1, Day 2, Day 7 and Follow-up phone call at 3-months.

Intervention

Index Procedure
Procedures Involved in the Use of the Device Under Investigation
Seraph 100 is intended for use with standard, commercially available bloodlines compatible with the pump system used. Refer to the IFU for description on specific instructions for use of the device under investigation, including any necessary handling requirements, preparation for use, any pre-use checks of safety and performance and any precautions to be taken after use.
Treatment Strategy or Treatment Procedures
If the subject is receiving supplemental IV iron during the treatments, the delivery of IV iron must be stopped during the trial period (day of procedure + 7 days of follow-up).
Systemic heparinization during hemodialysis with concomitant filtration with the Seraph 100 Filter is recommended with a 3-5-minute waiting period after the initial heparin bolus before beginning dialysis. Refer to the IFU for description on specific instructions.Treatment with Seraph 100 should be run at 250-350 mL/min for (4,5h ± 30 min. The treatment procedure will be in accordance with the IFU, except that specific blood samples will be taken before and after the Seraph 100 filter cartridge utilizing the bloodline sample ports in the stand-alone or combination configuration set-up (see Figure 1).
Blood samples will be taken at different timepoints during Day 0 visit in order to assess pathogen load (TTP):
• Treatment group: Day 0 will be considered as Treatment day being t=0 the moment immediately before the treatment with Seraph 100 starts.
• Control group: Day 0 will be considered the day when the randomization occurs and t=0 will be assessed as soon as the subject is randomized to control group, no later than 24 hours after randomization.
The timepoints at which the blood samples will be taken are specified in the following table. Blood samples at timepoint 5 minutes*, 45 minutes* and 2 hours* will not be taken for control group.

Study burden and risks

Anticipated Clinical Benefits
Benefits of the Seraph 100 Microbind Affinity Blood Filter may include potential reduction in the duration of bacteremia and the incidence of metastatic infections including, septic arthritis and osteomyelitis. As part of early treatment of sepsis, Seraph 100 could also theoretically prevent the development of multi-system organ dysfunction and lower mortality.

Risks associated with the specified device and procedure, together with their likely incidence, are described in the IFU. There may be risks related to the device under investigation that are unknown at present. Likewise, the exact frequency of the risk may be unknown.

Multiple risks assessments for the Seraph 100 device that includes use, design, and manufacturing have been conducted. The risks and mitigations have been performed to reduce the risk to As Low As Possible (ALAP) levels. Outcomes of this analysis has been shown that the potential benefit outweigh potential patient risks. Further, additional risks are associated with the operator error, damage during shipment, and not following the Clinical Trial Protocol. Further residual risks will be assessed as part of the outcome of the clinical trial.
Risks associated with the Seraph 100 Filter are similar to those associated with other filters used during extracorporeal treatment. Known and unexpected risks are relatively mitigated by working with an Investigator who is experienced and skilled in hemofiltration procedure with patients who show signs of sepsis. Additionally, the Investigator will be thoroughly trained on proper device properties and operation. Risks will also be minimized under this study protocol through adherence to the inclusion/exclusion criteria.
Complications that may occur may include the following, but are not limited to:
Potential Adverse Event

Hypotension
Cramps
Febrile reactions
Arrhythmia
Hemolysis
Hypoxemia
Thrombosis
Hematoma
Device failure/malfunction

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

1. Patients with sepsis and suspected bloodstream infection
2. Be >= 18 years old and <=90 years old
3. Adults receiving antibiotic therapy
4. Increase of at least two points of the Sequential Organ Failure Assessment (SOFA) score
5. Subjects that presents Procalcitonin (PCT) levels >0,5 ng/mL

Exclusion criteria

1. Subject is currently participating in another clinical investigation
2. Pregnant or nursing subjects and those who plan pregnancy during the clinical investigation follow-up period
3. Presence of comorbid conditions, or other medical, social, or psychological conditions that, in the investigator*s opinion, could limit the subject*s ability to participate in the clinical investigation or to comply with follow-up requirements, or impact the scientific soundness of the clinical investigation results

4. The first dose of the current antibiotic therapy was > 24 h before screening
5. Have Child-Pugh Class C cirrhosis
6. Have platelet count <30.000/uL
7. Contraindications for heparin sodium for injection
8. Subjects demonstrating any contraindication for this treatment as described in the IFU

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2020
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Seraph 100 Filter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-04-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	29-09-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-11-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT04260789
CCMO	NL71739.100.20