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Medium-term outcomes in patients with ascites treated with the alfapump® system: the TOPMOST study

Submission date 15/07/2019	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 27/08/2019	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 08/04/2024	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Ascites is a build-up of fluid between the two layers of the peritoneum. This is a membrane that lines the tummy (abdomen). Ascites is caused most commonly by liver cirrhosis and by cancer. The Sequana Medical alfapump® system is designed to remove ascites from the peritoneal cavity as it forms and move the ascites to the bladder where it is eliminated by the patient through normal urination.
The alfapump® system is a battery-powered pump that is implanted subcutaneously and is connected to two catheters; one to collect ascites from the peritoneal cavity and one to deliver the ascites to the bladder. The pump battery is charged transcutaneously (through the skin) by the patient. The alfapump® system is implanted using minimally invasive surgery and the physician can monitor the amount of ascites removed and adjust the removal rate using a dedicated computer (the alfapump® programmer) provided with the alfapump® system.
According to current clinical guides, the treatment of choice for refractory ascites is repeated paracentesis to evacuate fluid, associated with the administration of albumin.
In a series of Clinical Studies, the alfapump® system was shown to be an alternative to paracentesis in patients with refractory ascites due to liver cirrhosis.
This study will create an international registry of patients fitted with the alfapump® system. The main aim of the registry is to monitor the performance of the alfapump® system.

Who can participate?
All patients implanted with an alfapump® system

What does the study involve?
The TOPMOST is an international registry involving patients who are implanted with an alfapump® system according to its intended use and not participating in another clinical study in which the alfapump® is studied. Patients of both genders are eligible for this Registry. The Registry will include commercial implants of the alfapump® system implanted until 31 December 2023. It is expected this would be up to 400 patients.
Charts of all consecutive patients enrolled will be reviewed to obtain baseline data, safety and performance data on the alfapump® up to 24 month follow-up and standard of care lab results.

At select sites, additional questionnaire and health status information including nutrition, diet, quality of life, physical activity and body measurements will be taken. Also data on concomitant medication, ECOG status, Frailty Score and further standard of care lab results will be collected.

What are the possible benefits and risks of participating?
There is no direct benefit for patients from participating in the Registry. Participation in this registry gives doctors and regulatory authorities the possibility to follow how the alfapump® system is working and whether there are any problems with the system.
This is not a treatment study and there are no additional interventions or visits planned at the hospital so no additional risks are expected for patients included in the registry.

Where is the study run from?
Sequana Medical NV, Zurich, Switzerland

When is the study starting and how long is it expected to run for?
October 2018 to December 2025.

Who is funding the study?
Sequana Medical NV, Ghent, Belgium

Who is the main contact?
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT04326946

Secondary identifying numbers
2018-AAR-012

Study information

Scientific Title
inTernatiOnal alfaPuMp® cOhort STudy (TOPMOST)

Acronym
TOPMOST

Study objectives
The purpose of the study is to collect information on how the implanted ALFApump® system is working and how patients are doing before and after having received the ALFApump®. The information collected will tell how much fluid is being transported with the help of the pump, and if there is any need for extra paracentesis. The study will also collect information on what patients, as well as the physician, thinks about using the system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 06/09/2018, Swiss Ethics Committees on research involving humans (Haus der Akademien, Laupenstrasse 7, CH-3008, Bern; info@swissethics.ch; +41 31 306 93 95), ref: 2018-01173
2. Approved 16/11/2018, Ethics Committee University of Leipzig (Karl-Sudhoff-Institut für Geschichte der Medizin und der Naturwissenschaften, Käthe-Kollwitz-Straße 82, 04109 Leipzig; +49-(0)341 / 97 154 90; ethik@medizin.uni-leipzig.de), ref: 291/18-ek
3. Approved 18/06/2019, Ethics Committee Friedrich-Alexander-University of Erlangen (Erlangen-Nuremberg, Krankenhausstraße 12, 91054 Erlangen+49 9131 85-22270; ethikkommission@fau.de), ref: 201_19Bc
4. The alfapump® system is commercially available in the European Economic Area (EEA),

receiving CE marking for commercial activity under CE 616535 with Notified Body number 0086 (BSI).

Study design
Multi-centre open label observational cohort study.

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Refractory ascites due to liver cirrhosis or malignant ascites

Interventions
All consecutive patients treated with the alfapump® during the enrollment period are eligible for participation.
Patients are followed for a period of up to 24 months post-implant or until 30 days post explant.

The alfapump® system is implanted using minimally invasive surgery lasting 45 minutes. The procedure is typically performed under general anaesthesia but can also be performed under local anaesthesia with sedation. The pump is implanted under the skin in the right half of the abdomen via an incision of 3-4 cm. The catheters are implanted via a small open incision. The System is fully implanted, allowing the patient normal mobility and activity.

The study is a registry and no experimental interventional procedures are planned.
Patients will be attending visits according to routine care.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Not applicable.

Primary outcome measure
Patient survival with a functional alfapump® system at 6 months.
(An alfapump® system is considered functional when: capable of communication, can be

charged, there is an intact fluid pathway from peritoneal space to the bladder through the system, pump transported 80% of the target daily volume in the past 30 days)

Secondary outcome measures
1. Occurrence of (major) reportable events, adverse events, incidents and device deficiencies requiring a surgical intervention
2. Safety at 1-month post-implant for procedure-related incidents
3. Requirement for paracentesis
4. Clinical performance of the alfapump® system by monitoring ascites transport
5. Changes in occurrence of reportable events, all incidents as well as device deficiencies from up to 6 months pre-implant and post-implant.
6. Clinical impact of the alfapump® system by monitoring patient's clinical status, clinical chemistry, haematology laboratory data, MELD-Na, and ECOG
7. Quality of life changes
8. Overall survival

Overall study start date
16/10/2018

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. All patients implanted with an alfapump® system as per intended use

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
All patients implanted with an alfapump will be approached to participate in the registry. Planned to include up to 400 patients.

Key exclusion criteria
1. Younger than 18 years
2. Pregnancy
3. Inability to operate the Smart Charger to recharge the alfapump®
4. Participating in another study in which the alfapump® is studied

Date of first enrolment
17/10/2018

Date of final enrolment

31/12/2023

Locations

Countries of recruitment
Germany

Switzerland

Study participating centre
Inselspital
Freiburgstrasse
Bern
Switzerland
3010

Study participating centre
Universitätsklinikum Leipzig - Department für Innere Medizin Sektion Hepatologie
Liebigstraße 20
Leipzig
Germany
04103

Study participating centre
Chirurgische Universitätsklinik Erlangen
Krankenhausstr. 12
Erlangen
Germany
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Sponsor information

Organisation
Sequana Medical NV

Sponsor details
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Sponsor type
Industry

Website
http://www.alfapump.com

Funder(s)

Funder type
Industry

Funder Name
Sequana Medical NV

Results and Publications

Publication and dissemination plan
The results of the TOPMOST study may be submitted for publication. The plan is to report on a yearly basis interim results and a final report once the last patient has completed participation in this registry. Further analysis and reports may be decided on.

Intention to publish date
01/07/2026

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Not provided at time of registration