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Outpatient antibiotic therapy administered as a continuous infusion using a pump

Submission date
13/01/2026

Recruitment status
Recruiting

Registration date
26/01/2026

Overall study status
Ongoing

Last Edited
26/01/2026

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
For severe infections, intravenous antibiotic treatment is often necessary, and this typically requires hospitalization. Hospital admissions for this reason are increasing, but home-based treatment through Outpatient Parenteral Antibiotic Therapy (OPAT) offers a potential alternative for selected patients. A major challenge is that intravenous antibiotics are usually administered three to four times daily, making home-based administration highly resource-intensive. A novel solution involves elastomeric pumps (EP), which are replaced once a day and allow continuous infusion (CI) of antibiotics over 24 hours with minimal healthcare support (OPAT/EP). This approach appears promising but requires thorough evaluation of its effectiveness, patient safety, and impact on healthcare resource utilization. Therefore, this study aims to evaluate the effect of OPAT/EP regarding clinical and pharmacological treatment outcomes, cost-effectiveness and patient and provider satisfaction.

Who can participate?
All adults treated with intravenous antibiotic therapy for an infection and who need prolonged intravenous treatment, but who do not otherwise need inpatient hospital care are eligible for inclusion.

What does the study involve?
Eligible, consenting inpatients will transition to antibiotic treatment using CI with EP during hospitalization and then complete their treatment at home under OPAT/EP. Plasma antibiotic levels will be monitored to ensure dosing targets are achieved. Side effects, hospital-acquired infections, and other complications will be followed alongside treatment outcomes. Patients' and healthcare professionals' experiences will be assessed through questionnaires and focus group discussions. Additionally, a health economic analysis will compare the costs of OPAT/EP with conventional inpatient care and OPAT using intermittent administration.

What are the possible benefits and risks of participating?
The hypothesis is that OPAT/EP is a favourable treatment option, reducing hospital stays and overall care costs while improving convenience for both patients and healthcare providers. The

main benefit to the individual patient is the ability to be freer in their everyday life with OPAT /EP compared to conventional intermittent treatment, as the EP is changed once a day instead of 3-4 times daily.

Potential risks: OPAT/EP is a safe form of administration that has been used in other medical fields (e.g. oncology) and in other countries in the past. We do not expect worse outcomes for the patients who receive this treatment compared to patients who are given the current standard. However, to ensure that care is not inferior to OPAT/EP, outcomes and any adverse events will be closely monitored. Venous blood samples will be collected from patients. Venous blood sampling is done by puncture through the skin into a blood vessel in the arm. This can cause slight discomfort to the patient and also has a very small risk of infection. Information will also be collected from patients' medical records, and the risk of data being disclosed must always be considered. Other ethical issues that are considered are related to privacy in focus groups, where participants discuss perceptions of OPAT/EP and when responding to patient surveys. However, the questions that will be used are considered sensitive, and similar questions have been used in other studies when patients have been asked to give feedback on their experiences of the care received.

Where is the study run from?
Stockholm South General Hospital (Södersjukhuset), Sweden.

When is the study starting and for how long is it expected to run?
June 2025 to December 2027.

Who is funding the study?
Stockholm Region’s Innovation Fund, Sweden.

Who is the main contact:
Jaran Eriksen, specialist physician and Associate Professor, Karolinska Institutet and Stockholm South General Hospital, jaran.eriksen@ki.se

Contact information

Type(s)
Public, Scientific, Principal investigator

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Protocol serial number
ASN 2025-4706

Study information

Scientific Title
Outpatient Parenteral Antibiotic Therapy (OPAT) administered as continuous infusion by elastomeric pumps: Outcomes, pharmacokinetics, patient and staff experiences, and cost

Acronym
OPAT/EP

Study objectives
To evaluate the pharmacokinetics, treatment outcomes, adverse effects, economic aspects, as well as patient and staff perceptions of outpatient parenteral antibiotic treatment (OPAT) administered as continuous infusion using elastomeric pumps (OPAT/EP).

Specific Objectives:
1. To assess whether OPAT/EP achieves the same outcomes as intravenous intermittent antibiotic treatment in hospital.
2. To assess whether OPAT/EP achieves antibiotic plasma concentrations above MIC (minimum inhibitory concentration) for the bacteria being treated, throughout the whole treatment interval.
3. To measure stability of the antibiotic in the elastomeric pump throughout the dosing interval.
4. To assess the cost of using OPAT/EP in comparison to other care options.
5. To explore patients', patient relatives' and health care providers' perceptions of OPAT/EP.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/11/2024, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, Uppsala, 750 02, Sweden; +46-10-475 08 00; registrator@etikprovning.se), ref: Dnr 2024-06603-01

Primary study design
Observational

Study design
Observational study of outcomes, pharmacokinetics, patients and staff experiences and health economy of outpatient parenteral antibiotic treatment administered through elastomeric pumps.

Study type(s)
Efficacy, Quality of life, Safety, Other

Health condition(s) or problem(s) studied

Antibiotic treatment of infectious diseases, e.g. endocarditis, orthopaedic infections

Interventions
Patients will be included in the studies while they are still inpatients receiving antibiotic treatment with standard intermittent dosing. Patients will be recruited from the ID wards or our partner wards where ID consultants give daily recommendations for treatments, e.g. orthopaedics, surgery and internal medicine. Before being discharged to home care, three blood samples for measuring plasma antibiotic concentrations will be taken (peak concentration, trough concentration and mid-dosing interval concentration). All patients are then discharged to home care using outpatient parenteral antibiotic therapy using elastomeric pumps (OPAT/EP) that provide 24-hour continuous infusion of antibiotics. On day three with OPAT/EP, two blood samples for antibiotic plasma concentration measurement will be taken (through and mid-interval concentrations). Length of antibiotic therapy varies from days to weeks and patients will be followed until 30 days after ending antibiotic treatment.

Intervention Type
Drug/Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Antibiotic, elastomeric pump

Primary outcome(s)
1. Clinical outcome (clinical cure, readmission or death within 30 days of discharge from hospital) measured using data collected from patient medical records at 30 days after end of antibiotic treatment

Key secondary outcome(s)
1. Cost-effectiveness of a 24-hour elastomeric pump compared to intermittent treatment at home and intermittent treatment in the hospital measured using data collected from patient records and standard cost data from the Swedish National Board of health and Welfare at the end of the follow-up period

2. Adverse effects measured using data collected from patient records and questionnaires at the end of the follow-up period

3. Patient and health care professional experiences measured using focus group discussions at the end of the follow-up period

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Patients aged 18 years or older
2. Treated with intravenous antibiotic therapy for an infection and who need prolonged intravenous treatment, but who do not otherwise need inpatient hospital care

3. All bacterial infections falling in this category
4. Treatments using cloxacillin, piperacillin/tazobactam, vancomycin and benzylpenicillin
5. Patients who consent to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Inability to consent to participation for cognitive reasons, such as dementia
2. Insufficient knowledge of Swedish or English in combination with the absence of an authorized interpreter
3. Patients prescribed treatment other than those stated above (as stability for these antibiotics is poor and therefore cannot be given in the 24-hour continuous infusion pumps)

Date of first enrolment
01/06/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Sweden

Study participating centre
Södersjukhuset (Stockholm South General Hospital)
Sjukhusbacken 10
Stockholm
Sweden
11883

Study participating centre
AISH Access Care
Karolinska vägen 22
Stockholm
Sweden
17164

Study participating centre
Capio ASIH Dalen
Åstorpsringen 6
Enskededalen
Sweden
12131

Sponsor information

Organisation
Karolinska Institutet

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Not defined

Funder Name
Stockholm Region Innovation Fund

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be made available upon request from Jaran Eriksen, jaran.eriksen@ki.se

IPD sharing plan summary

Available on request