Self-administration in Outpatient Parenteral Antimicrobial Therapy service

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To assess feasibility of self-administration of intravenous antimicrobial therapy in the Dutch context.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56984

Source
ToetsingOnline

Brief title
SELF-OPAT

Condition

- Bacterial infectious disorders

Synonym
selfadministration of intravenous antimicrobial therapy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Wetenschapsfonds Amphia

Intervention

Keyword: Antimicrobial therapy, OPAT, Self-administration

Outcome measures

Primary outcome

To assess the feasibility of self-administration of intravenous antimicrobial therapy in the Dutch context. Feasibility is defined as adherence to the study protocol, which is defined as qualification for S-OPAT after training and completing an S-OPAT trajectory with a weekly scheduled nurse visit.

Secondary outcome

S-OPAT outcomes

- To investigate the number of scheduled and unscheduled S-OPAT related nurse visits to the patient

- To investigate the number of OPAT related (telephone) consultations (to the nurse and the hospital)

- To investigate the number of the different infusion devices (i.e. elastomeric pumps, infusion bags, infusion cassettes) used for S-OPAT patients in this study

- To investigate the time to discharge after signing up for OPAT

- The number of patients/caregivers who successfully complete S-OPAT training and are therefore qualified for self-administration. Successful completion of S-OPAT training is defined as the completion of the training for S-OPAT and the subsequent qualification (knowledge check and return demonstration) for S-OPAT trajectory by the nurse.

- To describe characteristics of patients/caregivers who successfully completed S-OPAT training versus patients who did not qualify for self-administration. Determinants taken into account are e.g. demographic factors (age, sex),

medical factors (indication, treatment duration, comorbidities), infusion factors (type of device).

- The number of patients/caregivers who finish their complete assigned S-OPAT trajectory.

- To describe characteristics of patients/caregivers who successfully completed their S-OPAT trajectory (with only a weekly scheduled nurse visit) versus patients who did not. Determinants taken into account are e.g. demographic factors (age, sex), medical factors (indication, treatment duration, comorbidities), infusion factors (type of device).

Cost outcomes

- To investigate the healthcare costs of S-OPAT

Clinical outcomes

- To investigate the clinical outcomes at day 30 after discharge. The following clinical outcomes are taken into account:

o Cure (defined as patients who completed S-OPAT and do not require IV antimicrobial therapy after the end of S-OPAT).

o Reinfection

o Duration of S-OPAT treatment

o Mortality

- To investigate the adverse events reported during the first 30 days after discharge.

Adverse events are categorized into line-related events and adverse drug events

(ADEs). Line-related events included mechanical complications (dislodgement, occlusion/clotting, malfunction, leakage) or infectious complications (catheter-related bloodstream infections, site irritation/infection (phlebitis)). Adverse events reported by health care professionals as well as self-reported adverse events by the patient were included.Ook nog ADE specificatie?

- To investigate the 30 day all-cause readmission rate after the end of the S-OPAT trajectory. Unexpected hospital admission post-discharge is defined as any readmission except for the scheduled admissions, such as elective surgeries or chemotherapies.
- To investigate the 30 day OPAT/infection related readmission rate of the S-OPAT trajectory

Satisfaction outcomes

- To investigate the patient satisfaction of S-OPATacceptability with S-OPAT
- To investigate the health-related quality of life (EQ-5D-5L questionnaire)

Study description

Background summary

The OPAT (Outpatient Parenteral Antimicrobial Therapy) service consists of providing antimicrobial therapy by parenteral infusion without hospitalization. The current practice is that a nurse visits the patient*s home daily to administer the antimicrobial therapy (healthcare professional, H-OPAT). However, OPAT can also be performed by the patient or caregiver. In this model the patient/caregiver administrates the intravenous antimicrobial (self-administration, S-OPAT). Internationally, S-OPAT is a well-established

practice, however research in the Netherlands on S-OPAT is lacking.

Study objective

To assess feasibility of self-administration of intravenous antimicrobial therapy in the Dutch context.

Study design

Prospective observational feasibility study

Study burden and risks

All patients will receive standard of care treatment. The only difference is that the patient/caregiver will be self-administering after qualification instead of a nurse visiting the patient for administration daily. Patient/caregiver will be thoroughly trained according to a standardized training and competency form. There is 24/7 supervision available in case the patient/caregiver is experiencing complications or has questions or concerns. In the case that the patient/caregiver is failing self-administration (after qualification), the patient will be deferred to the regular OPAT program (H-OPAT). All patients will be asked to fill out questionnaires. Patients may benefit from this study as they can administer the antimicrobial therapy when it is convenient for them, instead of waiting for the nurse to arrive and administer. Caregivers do not benefit from this study. Participation in this study is extra time investment for the caregiver (for training and daily administration)

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

- Aged 18 and over
- Hospitalized
- Treated with intravenous antimicrobial therapy and to be discharged with OPAT service
- To be discharged with OPAT service for a minimum of 5 days
- Central intravenous access in place
- Has a safe home environment (water, telephone, refrigerator available) and access to transport to hospital
- Able to understand written information and able to give informed consent
- Able and willing to perform self-administration, or able and willing to be self-administered by family members or other caregivers
- Able and willing to fill in questionnaires

Instead of the patient, a caregiver can also be eligible to perform self-administration. A caregiver is eligible if:
- Aged 18 and over
- Able to understand written information and able to give informed consent
- Able and willing to perform daily administration of intravenous therapy after following a training
- Patient is willing to get self-administered by this caregiver

Exclusion criteria

- Former participation in this study
- Discharge to a rehabilitation centre or nursing care centre (i.e. no discharge to home)
- Concomitant nursing care, if the patient requires other nursing care the

patient will be placed on nursing care and the nurses administer the medication during the concomitant nursing care
- More than two intravenous antimicrobial therapy required
- More than one intravenous administration device required (e.g. elastomeric pump and medication cassette)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-09-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL85913.078.24