Home-based management of hypoxemic patients with acute respiratory tract infections. A complex intervention study with a randomized controlled trial embedded in a regional collaborative healthcare network.

Published: 05-03-2025
Last updated: 25-03-2025

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Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON57335

Source
ToetsingOnline

Brief title
HOME-ART

Condition

- Respiratory tract infections

Synonym
lung infection, pneumonia, RTI

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW,Netwerk acute zorg

Intervention

Keyword: Continuous monitoring, Home treatment, hospital at home, Respiratory tract infection

Outcome measures

Primary outcome

The main study endpoint will be the clinical effectiveness of the intervention,

defined as the difference in mean number of days alive out of hospital (DOAH)

within 30 days after randomization.

Secondary outcome

Secondary study outcomes are feasibility of the intervention in a regional

network, safety (in terms of ICU admissions, delirium, all-cause mortality,

patient's experienced safety during the intervention, disability-free survival

within 30 days after randomization), health resources use, patient autonomy,

strain on informal carers, user satisfaction and cost-effectiveness of the

intervention.

Study description

Background summary

Community acquired respiratory tract infections (CA-ARTI) pose a high burden on our healthcare system. The continuous growing epidemiology of CA-ARTI, combined with the growing number of elderly and reduced capacity of healthcare workforce

demand novel approaches to deliver safe and efficient care. The HOME-ART intervention focusses on the development of a supported regional collaboration in which patients with CA-ARTI can be treated with extensive treatment in the at home setting. This includes oxygen treatment, intravenous antibiotic treatment (if required) and continuous monitoring of vital signs at home. This novel approach may have the potential to support patient autonomy and recovery while consequently reducing the use of scarce hospital resources.

Study objective

The main objective of this study is to assess the feasibility, safety and (cost-)effectiveness of the HOME-ART intervention in comparison to regular hospital admission in patients with CA-ARTI.

Study design

This study starts with a feasibility study (PART 1) among 10-15 patients from three hospitals in the Utrecht region, the Netherlands. After this, a multicentre randomized controlled trial (PART 2) will be performed in 2:1 ratio (home treatment : regular hospital care) in which we aim to include 252 patients in total. Besides quantitative data collection, the intervention and progress will be evaluated monthly during process evaluation cycles among involved stakeholders.

Intervention

For this HOME-ART intervention, we aim to align the medical treatment as closely as possible with regular hospital care. This means that patients who are randomized in the intervention group will receive oxygen therapy and/or intravenous antibiotics, if required. Furthermore, vital parameters including heart rate, blood pressure, oxygen saturation, respiratory rate and physical activity will be monitored continuously using a sensor (Checkpoint Cardio) and will be contacted by our medical coordination centre (MRC) to evaluate their health status. If indicated, patients will be additionally supported by visits of home care nurses. Patients randomized in the control group will receive regular hospital care.

Study burden and risks

This study may entail a small risk as well as benefits for the group of patients who are referred to the intervention group. These patients will not be treated in the controlled setting of the hospital, which could delay medical interventions if necessary. On the other hand, patients in the intervention group will wear a wearable sensor for 24/7 vital signs monitoring at home during the initial days of illness. This option allows the medical observation centre to keep an eye on possible deviating vital sign trend patterns during

the day and night which is much more than the current manual spot checks usually once every nursing shift once a patient is admitted to the hospital. With this option for the HOME-ART intervention, we expect to minimize the risk of any potential delays in medical interventions if needed. Furthermore, a hospital stay isn*t without risks for patients either. Patients could experience a delay in a medical intervention if patient deterioration is not recognized on time (for example during the night when usually no manual observations are done). In addition, home treatment could potentially reduce the risk of hospital-related infections and delirium and initiate a faster recovery in a patient*s own home environment which might be an additional benefit from participating in this study among patients in the intervention group. For all participants three questionnaires will be administered, requiring investments of participants* time.

Contacts

Public
Universitair Medisch Centrum Utrecht

Universiteitsweg 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Universiteitsweg 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet the following criteria:
- Mentally competent adult (>=18 years)
- Clinical diagnosis of community acquired respiratory tract infection in which hospital admission is considered required
- Availability of informal caregiver who is willing to provide support at home and agrees to participate in the study program and understands its implications after being informed by the research staff
- A good command of the Dutch language

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Patients who lack adequate digital proficiency to properly conduct digital aspects of the study
- Respiratory distress requiring more than 5 litres of oxygen therapy to achieve comfort and a saturation of >= 94% at discharge from ER and/or a patient with clinical signs of respiratory exhaustion
- Absence of haemodynamic stability at discharge from the ER, in which patient required > 2 500cc fluid challenges during ER admission and/or maintenance i.v. fluid suppletion is required
- Patients requiring follow-up diagnostics in clinical setting
- Serious risk of decompensation of pre-existent chronic illness, such as COPD, heart failure, immune deficiency, kidney- or liver failure, warranting hospital observation as judged by the responsible physician.
- Hospital admission 30 days prior to ED presentation.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2025
Enrollment:	252
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	05-03-2025
Application type:	First submission
Review commission:	METC NedMec

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	NL87901.041.24