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Out-of-hospital treatment of older adults with an acute moderate-to-severe lower respiratory tract infection or pneumonia

Submission date
18/09/2022

Recruitment status
No longer recruiting

Registration date
28/11/2022

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims

An acute moderate-to-severe lower respiratory tract infection (LRTI) or pneumonia in older adults is generally characterised by diagnostic uncertainty, a high risk of complications, and negative outcomes, including mortality. Care in the home situation often acutely falls short because of increased dependency due to falls, decline in activities in daily living (ADL) or a state of confusion. This often leads to a presentation at the emergency department (ED) with the goal to define the optimal treatment plan which usually consists of a combination of antimicrobials, oxygen suppletion and/or inhalation medication, treatment and/or prevention of delirium, and additional help in ADL; and the optimal treatment location. Although, these treatments can be organised outside the hospital, for example at home or in a nursing home, hospitalisation often occurs because of the 24/7 open access of EDs, and treatment outside the hospital is often considered irresponsible or impossible due to difficulties in ADL and the lack of (available) care.

Such hospitalisations of older adults can be considered unnecessary or avoidable when they are related to poor transmural collaboration and different treatment protocols between regional care partners (general practitioners (GPs), hospitals, nursing homes and homecare institutions), the lack of diagnostic and treatment possibilities in primary care, the lack of (acute) availability and capacity in nursing homes and homecare, or the presence of financial barriers. Especially in older adults, hospitalisations are associated with iatrogenic harm such as delirium, falls and functional decline. As a consequence, older patients often show further decline in ADL from these hospitalisations, and as a result are transferred to a nursing home or revalidation centre for further recovery. We hypothesise that these hospitalisations may be avoided when care is well coordinated between care partners.

Therefore, a multidisciplinary regional care pathway 'The Hague Respiratory Tract Infection (RTI) Care Bridge' was developed to support GPs with the diagnostics, treatment and organisation of care for older adults with an acute moderate-to-severe LRTI or pneumonia. In this care pathway, clear collaboration agreements were made between involved regional care partners. Three patients journeys were embedded in the care pathway: a hospital-at-home treatment, an ED-presentation with priority assessment, and admittance to a readily available recovery bed in a

nursing home. The care pathway includes a detailed guide upon treatment (e.g. antibiotics) and its monitoring.

In this prospective mixed methods study, the implementation of the care pathway will be evaluated. The primary aim of this study is to determine the feasibility of the care pathway, which is defined as the percentage of patients treated outside the hospital, according to the care pathway, whom fully complete their treatment without the need for hospitalisation within 30 days of follow-up. During this 12 months study period, it is hypothesised that in at least 75% of the older adults with an acute moderate-to-severe LRTI or pneumonia who are treated outside the hospital according to the care pathway, hospitalisation can be avoided. The secondary aims are to determine the safety of the care pathway (30-day mortality and occurrence of complications (readmissions, delirium, falls) within 30 days); the satisfaction, usability and acceptance of the care pathway; the total number of days of bedridden status or hospitalisation; sleep quantity and quality; functional outcomes, and quality of life. If possible, cost savings and logistical impact on hospital bed capacities will be evaluated.

Who can participate?
Older adults (age ≥65 years) who visit their GP or present at the ED with a clinical diagnosis of an acute moderate-to-severe LRTI or pneumonia. The informal caregivers and treating physicians of participating patients will also be asked to participate in the study.

What does the study involve?
The study will evaluate the feasibility, the safety, and the satisfaction, acceptance and usability of the care pathway; and will evaluate clinical outcomes (death rates, complications, satisfaction, sleep quality/quantity, functional outcomes and quality of life) between patients treated outside the hospital (at home or in a nursing home) and patients treated inside the hospital (control group).

What are the possible benefits and risks of participating?
As this is a mixed methods study evaluating the feasibility, safety and satisfaction of an integrated regional care pathway in common practice, there are no specific benefits nor risks to be expected from participation in the study. Patients receive stand care according to the care pathway or hospital guidelines. However, participation in the study will cost the patients (2.0-2.5 hours), informal caregivers (5-35 minutes) and treating physicians (5-35 minutes) extra time compared to not participating in the study.

Where is the study run from?
The study is run from the Haga Teaching Hospital in The Hague, the Netherlands.

When is the study starting and how long is it expected to run for?
The overall start date of the study was July 1, 2022. The recruitment start date will be December 1, 2022. The recruitment period will be one year (recruitment end date will be November 30, 2023). As the follow-up period of the study is one year, the overall trial end date will be November 30, 2024.

Who is funding the study?
1. Haga Teaching Hospital (Netherlands)
2. ZonMw / Netherlands Organisation for Health Research and Development (Netherlands)
3. MenzisFonds (Netherlands)
4. Dr. C.J. Vaillant Fonds (Netherlands)
5. Bavo stichting (Netherlands)

Who is the main contact?
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Scientific

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Additional identifiers

Protocol serial number
T22-066

Study information

Scientific Title
Evaluation of an integrated care pathway for out-of-hospital treatment of older adults with an acute moderate-to-severe lower respiratory tract infection or pneumonia

Acronym
The Hague RTI Care Bridge

Study objectives
Current study hypothesis as of 18/07/2023:

During this 12-month study period, it is hypothesised that in at least 75% of the older adults with an acute moderate-to-severe lower respiratory tract infection or pneumonia who are treated outside the hospital (at home or in a nursing home) according to the care pathway, hospitalisation can be avoided.

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Previous study hypothesis:

During this 12 months project, it is hypothesized that at least 50% of the (frail) elderly patients with an acute moderate-severe lower respiratory tract infection or pneumonia will not be admitted to the hospital (completely treated outside the hospital; at home or in the nursing home) after inclusion in the care pathway by the general practitioner or treating physician at the emergency department.

Ethics approval required
Old ethics approval format

Ethics approval(s)
On 25/07/2022, the Medical Research Ethics Committee Leiden Den Haag Delft (Postzone P5-P, Postbus 9600, 2300 RC Leiden; +31 (0)715265106; metc-ldd@lumc.nl) concluded that the Medical Research Involving Human Subjects Act does not apply to this study (ref: N22.078) and that it therefore was exempt for review by the Committee.

Primary study design

Interventional

Study design
Multicenter prospective mixed methods study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Out-of-hospital treatment (at home or in a nursing home) of older adults with an acute moderate-to-severe lower respiratory tract infection or pneumonia

Interventions
Current interventions as of 18/07/2023:

When a general practitioner (GP) decides to treat a patient at home or in a nursing home according to the care pathway, the GP will perform a physical examination, measure the vital parameters (heart rate, blood pressure, respiratory rate, oxygen saturation and temperature), and will perform the standard diagnostics package: nasopharyngeal swab for polymerase chain reaction (PCR) on respiratory pathogens (Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), influenza A/B, Respiratory Syncytial Virus (RSV)) and the adjusted Acute Presenting Older Patient (APOP) screening. The GP will inform the patient (or representative (e. g. in case of incapacity due to dementia/delirium)) about the study upon inclusion in the care pathway, and will ask for oral informed consent (IC). When a patient or representative (on behalf of the patient) agrees to participate in the study, the GP will hand over the patient information leaflet (PIL) and inform the research personnel about the patient. Within one workday, a research team member will visit the patient (and representative if applicable) on location to provide written IC and collect data.

When a patient does not want to participate in the study, no research data will be collected and the patient will still be managed according to the care pathway.

When the GP decides to refer a patient to the emergency department (ED) for additional assessment, a predefined diagnostics package will be performed on the ED: laboratory tests (blood cell count including differentiation, sodium/potassium, glucose, kidney function (creatinine/urea), C-reactive protein (CRP), and optional are d-dimer and N-Terminal pro Brain Natriuretic Peptide (NT-proBNP)), nasopharyngeal swab for PCR on respiratory pathogens (SARS-CoV-2, influenza A/B, RSV), clinical prediction rules (Pneumonia Severity Index (PSI) or CURB-65 score, and APOP), chest imaging (X-ray or CT-scan), and an electrocardiogram. All of the data above will be collected on the ED for patients included in the control group. The treating ED-physician will inform the patient (and representative if applicable) about the study (including handing over the PIL) upon inclusion in the care pathway (hospital-at-home treatment of admission in a nursing home) or upon hospitalisation for patients eligible for the control group, and will ask the patient (or representative if applicable) for oral IC to participate. Within one workday, a research team member will visit the patient (and representative if applicable) on location to provide written IC and collect data.

Besides the data from the registration forms of the patients in the hospital-at-home group, GPs will collect information regarding illness duration during their treatment and monitoring of the patient, thereby providing insight into the occurrence of complications (readmissions, delirium, falls), and the percentage of complete treatments at home. The elderly care physicians will

collect similar information in the electronic health records (EHRs) of patients in the nursing home group. For patients in the control group, this information will be extracted from the hospital EHRs.

A research team member will visit the patient on location (at home, in the nursing home or in the hospital) on the first workday after the start of treatment. During this visit, patients (and their representatives if applicable) will be able to ask additional questions about the PIL and the study. If a patient (or representative on behalf of the patient) agrees to participate in the study, written IC will be asked for participation in the study. In case a representative has provided written IC for an incapacitated patient (e.g. in case of delirium), and the patient's medical condition improves over time, the patient will be asked for written IC when the patient is considered competent again. When a patient has given written IC, their informal caregiver and treating physician will also be approached to participate in the study.

During this first visit (+/- 1 hour), baseline information will be collected from the patient. This baseline information will include demographic information (including ethnicity/religion) and a geriatric assessment (GA). Ethnicity and religion are included in the demographic information as the area of The Hague has a multicultural society and these factors may influence a patient's care system, and thereby the choice of the treatment location. Dementia research has shown that a considerable amount of the people with a migration background makes limited use of professional homecare, and needed care is often taken over by family members. A GA is an evidence-based, systematic procedure used to objectively describe the health status of older adults, focusing on somatic, functional, and psychosocial domains; and aimed at constructing a multidisciplinary treatment plan. As our study population consists of patients who are in a vulnerable phase of life, we want to keep the study load as low as possible. The GA will include the following validated tests: the Charlson Comorbidity Index, G-8 screening tool, 6-item cognitive impairment test (6-CIT), functional status (KATZ-15 and living situation) and quality of life (QoL) (EQ-5D-5L) one week prior to the onset of disease. During this visit, patients will also be given a core Consensus Sleep Diary to fill in on the two upcoming days and on the seventh day after inclusion. Besides that, patients will be given a Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance short form 8b to fill in on the seventh day after inclusion. The sleep quality/quantity forms will be collected one week after inclusion. In the hospital-at-home group, the registration forms will be collected together with the monitoring kits when the patient is released from the care pathway.

Two-three weeks after inclusion, a semi-structured in-depth interview (+/- 30 minutes) will be held on voluntary basis with the first ten patients in the hospital-at-home group, the nursing home group and the control group. If these ten patients in each group agree to participate in the interview, their informal caregivers will also be asked if they want to participate in a similar interview to collect information about their experiences with the received/given care. The interview of the patient and their informal caregiver can take place simultaneously. If the patients in the hospital-at-home group agree to participate in the interview, their GPs will also be asked for an interview about their experiences with the care pathway. This interview with the GP will take place separately. By selecting participants in this way, the interview will be taken without purposive sampling.

The framework that is used to develop the interview guide is the Consolidated Framework for Implementation Research (https://cfirguide.org/), which provides a framework of constructs that have been associated with effective implementation. There are five different domains with corresponding example questions. These questions have been adapted and tailored to the intervention program, and will form the basis for a process evaluation of the implementation of the care pathway focusing on the implementation, the mechanisms of impact, and context

(facilitators and barriers to implementation). The information collected during these interviews will be used to adjust the care pathway.

At 30 days, all patients will receive a phone call (or a visit at request of the patient) from a research team member (+/- 30 minutes) in which they will be asked about the occurrence of complications (readmissions, delirium, falls), sleep quality (PROMIS Sleep Disturbance short form 8b), functional status (KATZ-15 and living situation), QoL (EQ-5D-5L) and their satisfaction. The questions to evaluate satisfaction are based on the Consumer Quality Index, Patient Reported Outcomes Measures and other research evaluating the out-of-hospital treatment of patients, and adjusted if applicable.

At 30 days, all participating informal caregivers and treating physicians (GPs, elderly care physicians and hospital ward doctors) will receive a short phone call (+/- 5 minutes) from a research team member in which they will be asked about their satisfaction, usability and acceptance of the care pathway. In this call, treating physicians will also be asked about the occurrence of complications.

At six and twelve months, all patients will receive a phone call (or a visit at request of the patient) from a research team member (+/- 15 minutes) in which they will be asked about their functional status (KATZ-15 and living situation) and QoL (EQ-5D-5L).

The research group has longstanding experience in performing questionnaires by telephone in the older population, which has proven to be feasible and was validated in previous studies.

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Previous interventions:

If the general practitioner decides to treat the patient at home according to the care pathway, the general practitioner will perform a physical examination, measure the vital parameters (heart rate, blood pressure, respiratory rate, oxygen saturation and temperature) and will perform the standard diagnostics package: nasopharyngeal swab (SARS-CoV-2 and influenza) and adjusted APOP-screening. The general practitioner will inform the patient (and representative (e.g. in case of incapacity due to dementia/delirium)) about the study and ask for oral informed consent to collect data for scientific purposes. If the patient or representative (on behalf of the patient) agrees to participate in the study, the general practitioner will hand over the patient information letter and inform the research personnel about the patient. Within 1 workday, a research team member will visit the patient (and representative if applicable) at home to provide written informed consent and collect data. If the patient refuses to participate in this study, no research data will be collected and the patient will be managed according to the regional care pathway anyway.

When the general practitioner decides to refer the patient to the emergency department for additional assessment, a predefined diagnostics package will be performed on the emergency department: laboratory tests (blood cell count including differentiation, C-reactive protein (CRP), sodium/potassium, glucose, kidney function (creatinine/urea), and optional are d-dimer and NT-proBNP), clinical prediction scores (PSI-score or CURB-65 score, and APOP-score), nasopharyngeal swab for a PCR on respiratory pathogens (SARS-CoV-2 and influenza), chest imaging (X-ray and/or CT-scan) and an electrocardiogram (ECG). All of the data above will be collected on the emergency department for patients included in the control group. The treating physician on the emergency department will inform the patient (and representative if applicable) about the study (including handing over the patient information letter) upon

inclusion in the care pathway (hospital-at-home treatment or admission nursing home) or upon hospitalization for patients eligible for the control group, and will ask the patient (or representative if applicable) for oral informed consent to participate in the study.

Most patients included in the care pathway and in the control group will receive some form of antimicrobial therapy. For the patients in the hospital-at-home track, the nurse from the homecare institution will also check at the explanatory visit (<4 hours after inclusion) whether patients already received their first dose of antimicrobial therapy, otherwise the patients will receive their first dose of antimicrobial therapy by the nurse. The patients/caregivers/nurses in the hospital-at-home track will be checking the vital parameters of the patient at least three times a day and write them down on the given registration form to discuss them with the treating general practitioner together with whether the patient went out of bed that day and whether the patient has fallen. The general practitioners (hospital-at-home) and specialists in elderly care medicine (admittance on a recovery bed in a nursing home) will collect information regarding illness duration during their follow-up, thereby providing information about mortality, complications (delirium, falls, readmissions) and percentage of complete treatments at home or the nursing home.

A member of the research team will visit the patient at home or in the nursing home on the first day after inclusion in the care pathway and in the hospital when included in the control group. During this visit, patients (and their representatives if applicable) will be able to ask additional questions about the patient information letter and the study. If a patient (or representative on behalf of the patient) agrees to participate in the study, he/she will be asked to give written informed consent for participation in the study. In case a representative has given written informed consent for an incapacitated patient (e.g. in case of delirium), and the patient's medical condition improves over time, the patient will be asked for written informed consent when the patient is considered competent again. During this visit (+/- 1 hour), baseline information will be collected from the patients that gave written informed consent. This baseline information will include demographic information (including ethnicity/religion) and a geriatric assessment. Ethnicity and religion of patients are included in the baseline information as the Haaglanden area has a multicultural society and these factors may influence a patient's care system and thereby the choice for the current treatment location. Dementia research has shown that a considerable amount of people with a migration background make limited use of professional home care, and the care is often taken over by family members. A geriatric assessment is an evidence-based way of describing different domains that are associated with ageing in the older population and focuses on older adults' functional, psychosocial and medical capacities. As our study population consists of patients who are in a vulnerable phase of life, we want to keep the study load as low as possible. The following tests will be included in the geriatric assessment: the Charlson Comorbidity Index, G-8 screening tool, 6-item cognitive impairment test (6-CIT), KATZ-15, current living situation and quality of life (EQ-5D-5L) one week prior to the onset of disease. During this visit, patients will also be given a core Consensus Sleep Diary to fill in on the two upcoming days and on the seventh day after inclusion. Patients will also be given a PROMIS Sleep Disturbance short form to fill in on the seventh day after inclusion. The homecare nurses will collect the registration and sleep quality/quantity forms at their last patient visit (after a patient is released from the pathway) together with the monitoring kits. After this first visit, the research team member who visited the patient will also contact their caregiver and treating physician to ask for written informed consent for participation in the study.

With the first ten patients included in the hospital-at-home group of the care pathway, a semi-structured in-depth interview (+/- 30 minutes) will be held on a voluntary basis with the patient within three weeks after inclusion in the care pathway. If these 10 patients agree to participate in the interview, their caregivers and their treating general practitioners will also be asked if

they agree to undergo the same interview to collect information about their experiences with the care pathway. The interview of the patient and their caregiver can take place simultaneously, while the interview with the general practitioner will take place separately. The framework that will be used to develop the interview guide is the Consolidated Framework for Implementation Research (https://cfirguide.org/), which provides a framework of constructs that have been associated with effective implementation. There are five different domains with corresponding example questions. These questions will be adapted and tailored to the intervention program. The information collected during these interviews will be used to adjust the care pathway based on the experiences of patients, caregivers and general practitioners with the hospital-at-home treatment.

At 30 days, all patients (both patients included in the care pathway and in the control group) will receive a phone call (+/- 30 minutes) from one of the research members in which they will be asked about their sleep quality (PROMIS Sleep Disturbance short form), their functional status (KATZ-15 and current living situation (at home with or without homecare, or in a nursing home)), their quality of life (EQ-5D-5L), their satisfaction with the given care/treatment and the development of complications (for example readmissions, falls and delirium).

At 30 days, all patients their caregivers and treating physicians (general practitioners, specialists in elderly care medicine and ward doctors in the hospitals) will receive a short phone call (+/- 5 minutes) from one of the research members in which they will be asked about their experiences with the given care/treatment. During this call, the treating physicians will also be asked about the development of complications (for example readmissions, falls and delirium).

At 6 and 12 months, all patients (both patients included in the care pathway and in the control group) will receive a phone call (+/- 15 minutes) from one of the research members in which they will be asked about their functional status (KATZ-15 and current living situation (at home with or without homecare, or in a nursing home)) and quality of life (EQ-5D-5L).

Patients can choose whether the questionnaires at 30 days, 6 months and 12 months will be either sent by post or email or performed by telephone to maximize follow-up response rates. The research group has longstanding experience in performing questionnaires by telephone, and this has proven to be feasible and has been validated in previous studies.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 18/07/2023:

Feasibility of the care pathway, which is defined as the percentage of patients treated outside the hospital, according to the care pathway, whom fully complete their treatment without the need for hospitalisation within 30 days of follow-up. This will be measured by the amount of hospitalisations within 30 days of follow-up in patients treated outside the hospital, by using the registration forms, electronic health records (EHRs) and the 30-day questionnaires.

Previous primary outcome measure:

Feasibility of the care pathway is defined as the percentage of patients included in the care pathway that were not admitted to the hospital (treated outside the hospital). Feasibility will be

measured on day 30 using the registration forms, electronic health records (EHRs) and the 30-day questionnaires.

Key secondary outcome(s)

Current secondary outcome measures as of 18/07/2023:

1. The safety of the care pathway will be measured using the 30-day mortality and occurrence of complications (readmissions, delirium, falls) within 30 days. This data will be measured using the registration forms, electronic health records (EHRs) and the 30-day questionnaires
2. The satisfaction, usability and acceptance of the care pathway will be measured using the 30-day questionnaires (with a five or ten point Likert scale) in patients, informal caregivers and treating physicians; and semi-structured interviews with the first ten patients and informal caregivers in the hospital-at-home group (and treating general practitioners), nursing home group and control group
3. Total number of days of bedridden status or hospitalisation will be measured on day 30 using the registration forms and EHRs
4. Sleep quantity measured by the core Consensus Sleep Diary on the first two days and on the seventh day after inclusion
5. Sleep quality measured by the Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance short form 8b on day 7 and 30 after inclusion
6. Functional outcomes will be measured by questionnaires (KATZ-15 and living situation) at 30 days, six and twelve months
7. Quality of life (QoL) will be measured by questionnaires (EQ-5D-5L) at 30 days, six and twelve months

If possible:
8. Cost savings will be roughly measured using the length of the hospital or nursing home admission, or homecare use; and the average care costs per day for care in a hospital, care in a nursing home or homecare
9. Logistical impact on hospital bed capacities will be roughly estimated by simulating a scenario in which the patients treated outside the hospital (at home or in the nursing home) would have been admitted to the hospital at the time of care pathway inclusion

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Previous secondary outcome measures:

1. Practical applicability of the care pathway (defined as the percentage of patients that can be included in the care pathway and that are actually included) will be measured using the amount of phone registrations of patients at the home care contact centre and the specialists in elderly care medicine, and the actual amount of inclusions in the care pathway after 1 year
2. 30-day mortality will be measured on day 30 using the registrations forms, EHRs and the 30-day questionnaires
3. Complications (readmissions, delirium, falls) within the first 30 days will be measured on day 30 using the registration forms, EHRs and the 30-day questionnaires
4. Satisfaction of patients, their caregivers and treating physicians with the given care, measured using satisfaction questionnaires on day 30, and semi-structured in-depth interviews with the first 10 patients/caregivers/general practitioners in hospital-at-home treatment at weeks 2-3
5. Days of bedridden status or hospitalization will be measured on day 30 using the registration forms and EHRs
6. Sleep quantity measured by the core Consensus Sleep Diary on days 1, 2 and 7
7. Sleep quality measured by the Patient-Reported Outcome Measurement Information System

(PROMIS) Sleep Disturbance short form on day 7 and day 30
8. Functional outcomes will be measured by questionnaires (KATZ-15 and current living situation) on day 30, 6 and 12 months
9. Quality of life will be measured by questionnaires (EQ-5D-5L) on day 30, 6 and 12 months

If possible:
10. Cost savings will be roughly measured using the length of the use of care (length of hospital stay or nursing home stay, length of home care) and the average costs per day for care in the hospital, in the nursing home or home care after all other data is collected
11. Logistical impact on hospital bed capacities will be measured by simulating a scenario in which the patients who were treated at home or in the nursing home would have been admitted to the hospital at the time of care pathway inclusion after all other data is collected

Completion date
30/11/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/07/2023:

To be eligible to participate in this study, a patient must meet all of the following criteria:
1. Age ≥65 years
2. Clinical diagnosis of an acute moderate-to-severe (Pneumonia Severity Index (PSI) class ≥3 or CURB-65 ≥2) lower respiratory tract infection or pneumonia
3. Oxygen saturation ≥92% and respiratory rate ≤24/minute with maximum five litres of oxygen (or adjusted oxygen saturation cut-offs as clinically indicated (e.g. for patients with chronic obstructive pulmonary disease (COPD)) by the treating physician)
4. Written informed consent (IC) for participation in the study

To be eligible to participate in this study, an informal caregiver must meet all of the following criteria:
1. Age ≥18 years
2. Being an informal caregiver of a patient included in the study
3. Written IC for participation in the study

To be eligible to participate in this study, a treating physician must meet all of the following criteria:
1. Physician of a patient included in the study at the main location of treatment
2. The physician should have treated the patient at least ≥2 (consecutive) days
3. Written IC for participation in this study

Patients who fulfil the inclusion criteria and do not meet the exclusion criteria of the care pathway, and are hospitalised on weekdays outside office hours (18:00-08:00) or weekend days due to inactivity of the care pathway, will serve as a control group.

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Previous inclusion criteria:

To be eligible to participate in this study, a patient must meet all the following criteria:
1. Age ≥65 years
2. Clinical diagnosis of an acute moderate-severe* lower respiratory tract infection or pneumonia
3. Written informed consent for participation in the study
4. Oxygen saturation ≥92% with a maximum of 5 litres O_2** and a respiratory frequency ≤24 /minute

*: moderate-severe is defined by a Pneumonia Severity Index class ≥3 or a CURB-65 ≥2
** = or adjusted oxygen saturation cut-offs for the patient as clinically indicated (for example for patients with chronic obstructive pulmonary disease) by the treating physician

To be eligible to participate in this study, a caregiver must meet all the following criteria:
1. Age ≥18 years
2. Caregiver of a patient included in the study
3. Written informed consent for participation in the study

To be eligible to participate in this study, a physician must meet all the following criteria:
1. Physician of a patient included in the study at the main location of treatment: hospital-at-home (general practitioner), nursing home (specialist in elderly care medicine) and hospital (ward doctor)
2. Physician should have treated the patient for at least ≥2 (consecutive) days
3. Written informed consent for participation in the study

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
65 Years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 18/07/2023:

A potential patient who meets any of the following criteria will not be able to participate:
1. Chemotherapy for solid organ malignancy (<2 months before presentation)
2. Active hematologic malignancy
3. Immunocompromised status (e.g. solid organ transplants)
4. Severe dementia (Clinical Dementia Rating Scale Sum of Boxes (CDR-SOB) score 16-18)

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Previous exclusion criteria:

A potential patient who meets any of the following criteria will not be able to participate:
1. Patients receiving chemotherapy (<2 months before presentation)
2. Patients with active hematologic malignancy
3. Immunocompromised patients (for example solid organ transplants)
4. Severe dementia (clinical dementia rating scale sum of boxes score 16-18)

Date of first enrolment
01/12/2022

Date of final enrolment
30/11/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
Haga Teaching Hospital
Els Borst-Eilersplein 275
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2545AA

Study participating centre
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Lijnbaan 32
The Hague
Netherlands
2512VA

Study participating centre
Hadoks
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Netherlands
2517JK

Sponsor information

Organisation

Haga Hospital

ROR
https://ror.org/03q4p1y48

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Haga Teaching Hospital

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
MenzisFonds

Funder Name
Dr. C.J. Vaillant Fonds

Funder Name
Bavo stichting

Results and Publications

Individual participant data (IPD) sharing plan

Current Individual participant data (IPD) sharing plan as of 18/07/2023:

The written informed consent forms will be safely stored in a locker at the internal medicine research department of the Haga Teaching Hospital. The data will be stored using Castor EDC. The data will be coded in the Haga Teaching Hospital. The key of the coded dataset will be stored on a secured drive in the Haga Teaching Hospital. The datasets, including the coded participant-level data, will be made available to other researchers upon reasonable request after publication of the results. Requests should be directed to Rick Roos (r.roos@hagaziekenhuis.nl). Data requestors will need to sign a data access agreement. These datasets will only contain the coded individual-level data that underlie the results in the publication the researcher is referring to in his/her request. Study participants will be asked for their consent to share their coded data upon reasonable request with other researchers.

Previous Individual participant data (IPD) sharing plan:

The datasets will be stored in Castor EDC. The written informed consent forms will be safely stored at the research department of the internal medicine of the Haga Teaching Hospital and the dataset key will be stored in a secured drive of the Haga Teaching Hospital. The datasets including the coded participant-level data will be made available to other researchers upon reasonable request by Rick Roos (r.roos@hagaziekenhuis.nl) after the publication of the results. These datasets will only contain the coded individual-level data that underlie the results in the publication the researcher is referring to in his/her request. Participants will be asked for their consent to share their coded data upon reasonable request with researchers in other countries within the European Union, and with researchers in countries outside the European Union where the privacy rules of the European Union do not apply.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/08/2023	18/08/2023	Yes	No
Participant information sheet	Informal caregiver version 2.1	28/11/2022	28/11/2022	No	Yes
Participant information sheet	Patient version 2.1	28/11/2022	28/11/2022	No	Yes
Participant information sheet	Physician version 2.1	28/11/2022	28/11/2022	No	Yes
Participant information sheet	Informal caregiver version 3.0	18/07/2023	19/07/2023	No	Yes
Participant information sheet	Patient version 3.0	18/07/2023	19/07/2023	No	Yes

Participant information sheet	Physician version 3.0	18/07/2023	19/07/2023	No	Yes
Protocol file	version 3	04/11/2022	28/11/2022	No	No
Protocol file	version 4	17/07/2023	18/07/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes