Subject information for participation in medical research

The Hague RTI Care Bridge

Official title: Evaluation of an integrated care pathway for hospital-at-home treatment for elderly with an acute moderate-severe lower respiratory tract infection or pneumonia.

Introduction

Dear Sir/Madam,

With this letter, we would like to ask you to take part in a medical study. Participation is voluntary. You have received this letter because your doctor has diagnosed you with an acute lower respiratory tract infection or pneumonia.
You can read about the medical study in this information sheet, what it means for you, and what the pros and cons are. It is a lot of information. Can you please read the information and decide if you want to take part? If you want to take part, complete the form in **Appendix B**.

Ask your questions
You can take your decision based on the information in this information sheet. We also suggest that you do this:
- Put your questions to the investigator who gave you this information.
- Talk to your partner, family or friends about this study.
- Ask questions to the independent expert: Dr. Iwan. A. Meynaar.
- Read the information on www.rijksoverheid.nl/mensenonderzoek.

1. General information

This research is coordinated by the Haga Teaching Hospital in collaboration with general practitioners united in Hadoks, Haagse Wijk en Woonzorg, Spoedzorg Haaglanden, the Haaglanden Medical Centre (HMC), the Leiden University Medical Centre (LUMC) Health Campus The Hague and Florence. Below, we refer to the Haga Teaching Hospital as the 'client' for the sake of convenience. Researchers, which can be physicians, physician researchers, medical students and research nurses, conduct the research in various general practices, nursing homes and hospitals.

This study requires approximately 100 patients with an acute lower respiratory tract infection or pneumonia from various general practices and hospital in the The Hague region, ideally 50 patients being treated at home or in a nursing home and 50 patients being treated in hospital. The caregivers and treating physicians of all patients will also be approached for participation in order to analyse the satisfaction with the given care from all different perspectives.

The management of the Haga Teaching Hospital has approved the implementation of this research within the Haga Teaching Hospital. The Medical Ethics Review Committee (METC) Leiden The Hague Delft has issued a statement for this research that the 'research is not subject to the WMO'. This means that this research has been registered by the researchers with this METC and does not fall under the Medical Research Involving Human Subjects Act.

2. What is the purpose of the study?

The doctor has just diagnosed you with a lower respiratory tract infection or pneumonia. In many cases, such an infection must be treated with a combination of antibiotics/viral inhibitors, oxygen and/or inhalation medication. In principle, this kind of treatment could also be given to patients at home. However, elderly (age 65 years or older) with a lower respiratory tract infection or pneumonia are often hospitalized. Hospitalized elderly are at greater risk of complications such as malnutrition, confusion, falls and conditional decline.

In many cases, elderly are hospitalized because the care between the involved regional care partners (for example: general practitioners, hospitals, nursing homes and home care organisations) is not properly coordinated. That is why the care pathway 'The Hague RTI Care Bridge' has been developed together with all involved regional care partners to support general practitioners in their choices regarding the diagnostics, the treatment of and the organisation of care for elderly with a lower respiratory tract infection or pneumonia.

This care pathway includes three possible routes for elderly with a lower respiratory tract infection or pneumonia from which general practitioners can choose:
- hospital-at-home treatment
- presentation at the Emergency Department (ED) of the Haga Teaching Hospital or Haaglanden Medical Centre (HMC)
- temporary admission to a nursing home

In this study, we want to assess the feasibility and practical applicability of the care pathway 'the Hague RTI Care Bridge'. Besides that, we want to look at the influence of treatment at home or in a nursing home compared to treatment in a hospital. Therefore, we will, among other things, look at the occurrence of complications (such as confusion (delirium) and falls), physical condition, quality of life and sleep. In addition, we also pay specific attention to the experiences of patients, their informal caregivers and their treating physicians.

3. What is the background of the study?

In many cases, elderly are hospitalised because the care between the involved regional care partners (e.g. general practitioners, hospitals, nursing homes and home care organisations) is not properly coordinated. Therefore, an acute lower respiratory tract infection or pneumonia in elderly often leads to unnecessary long hospitalisations with a high risk of complications, such as malnutrition, delirium and falls. That is why the care pathway 'The Hague RTI Care Bridge' has been developed together with all involved regional care partners.

The care pathway includes three routes that general practitioners can follow for elderly with an acute lower respiratory tract infection or pneumonia. The central principle in this is that the patient receives the right care in the right place. In the care pathway, clear collaboration agreements are made about this between the regional care partners. It is expected that the application of this care pathway will reduce the number of unnecessary hospital admissions of elderly with an acute lower respiratory tract infection or pneumonia by at least 10% in 12 months.

4. What happens during the study?

How long will the study take?
Are you as patient participating in the study? In that case, study participation will take you approximately 12 months in total.

Step 1: Are you eligible to take part?
First, we want to know if you are eligible to participate. The first step in this is the assessment by the general practitioner or the treating physician at the ED according to the agreements in the care pathway. If you are 65 years or older and your general practitioner or the treating physician in the ED has diagnosed you with an acute lower respiratory tract infection or pneumonia, you may be eligible for treatment according to the care pathway.

If you are registered on a work day during office hours (08.00-18.00) for the hospital-at-home treatment through the care pathway, you are eligible to participate in the study. If you are registered on a work day or weekend day (08.00-20.00) for the temporary admission to a nursing home, you are also eligible to participate in this study.

It can occur that you presented on a work day outside office hours (18.00-08.00) or a weekend day and are eligible for the hospital-at-home treatment or the temporary admission to a nursing home through the care pathway, but are admitted to the hospital due to the inactivity of the care pathway or unavailability of the recovery bed. You will still be eligible to participate in this study.

If you decide to participate in the study, a member of the research team (Haga Teaching Hospital) will contact your general practitioner, nursing home doctor or consult your electronic health record to collect information about your medical history, your medication, your test results (blood tests, corona test, etc.) and the length of hospital stay. You give consent for this on the consent form.

Step 2: Study and measurements
It is not necessary for you to visit the hospital more often for the study. You will be contacted for the study a total of four times (once physically and three times by phone). All patients who receive the hospital-at-home treatment through the care pathway have a form on which, among other things, heart rate, oxygen level and temperature can be noted three times a day

for their consultations with their general practitioners. The first ten patients (and their informal caregivers and general practitioners) who receive the hospital-at-home treatment through the care pathway will also be asked whether they voluntarily agree to an in-depth interview about their experiences with the treatment at home.

1st Contact moment: 1 day after the start of participation

One member of the research team (Haga Teaching Hospital) will visit you at home, in the nursing home or in the hospital to complete a questionnaire (approximately 1 hour), focusing in particular on your background (ethnicity, religion, support system, medical history), your daily functioning (such as physical condition and memory) and quality of life prior to getting a lower respiratory tract infection or pneumonia. Attention will also be paid to medical history and medication. During this visit, you will also receive a sleep diary and questionnaire about sleep quality. These will be collected by a member of the research team after one week.

2nd Contact moment: 30 days after the start of participation

One member of the research team (Haga Teaching Hospital) will contact you by phone to complete a questionnaire (approximately 30 minutes), focusing in particular on your daily functioning (physical condition, daily activities), quality of life, your current living location (at home with or without home care; or in a nursing home) and the occurrence of complications (such as a fall). You will also be asked about your satisfaction with the provided care.

3rd and 4th contact moment: 6 and 12 months after the start of participation

One research team member (Haga Teaching Hospital) will contact you briefly by phone to complete a questionnaire (approximately 15 minutes), focusing in particular on your daily functioning (physical condition, daily activities), your quality of life and your current living location (at home with or without home care; or in a nursing home).

Optional contact moment after 2-3 weeks (10 patients in the hospital-at-home group)

A member of the research team (Haga Teaching Hospital) will visit the first 10 patients receiving the hospital-at-home treatment at home for an interview if they have given consent for it. If you give consent for this, the interview will be recorded with a recorder. This interview (approximately 30 minutes) will mainly focus on your experiences with the received hospital-at-home treatment. This interview will if possible be combined with the interview of your informal caregiver. The interview with the general practitioner about his/her experiences will be conducted separately. The information from these interviews is used to adjust the care pathway if necessary.

What is the difference with standard care?

You will receive the medical care you need regardless of whether or not you participate in this study. Your general practitioner will assess whether you can be treated at home and if your general practitioner estimates that this is not feasible or if it turns out that the necessary care cannot be organised at home in time at that time, you will be referred to the hospital.

5. What agreements do we make with you?

We want the study to go well. That is why we want to make the following agreements with you:

- You should contact the investigator in these situations:
  - You are hospitalised or get treatment in a hospital.
  - You no longer want to take part in the study.
  - Your telephone number or email address changes.

6. What side effects, adverse effects or discomforts could you experience?

In principle, no side effects, adverse effects or inconveniences are to be expected when taking the questionnaires and the interview.

7. What are the pros and cons if you take part in the study?

If you participate in this research, it does not mean that you will suffer less from you lower respiratory tract infection or pneumonia. But if you take part you will help the investigators to get more insight into the treatment of elderly with a lower respiratory tract infection or pneumonia at home.

Taking part in the study can have this con:

- Study participation will cost you extra time due to the questionnaires.

You do not wish to participate in the study?

It is up to you to decide if you wish to participate in the study. You do not wish to participate? In that case, you will receive the same treatment for your acute lower respiratory infection or pneumonia. Your doctor can tell you more about the available options for treatment. And about the pros and cons.

8. When does the study end?

The investigator will let you know if there is any new information about the study that is important to you. The investigator will then ask you if you want to continue to take part.

In these situations, the study will stop for you:

- The end of the study has been reached. This is one year after you started participating in this study.
- You want to stop participating in the study yourself. You can stop at any time. Report this to the investigator immediately. You do not have to explain why you want to stop. You can then discuss with your physician how you would like to be treated further.
- The investigator thinks it is better for you to stop.
- One of the following authorities decides that the study should stop:
  - the Haga Teaching Hospital
  - the government, or

- the Medical Ethics Review Committee assessing the study

What happens if you stop participating in the study?
The investigators use the data that have been collected up to the moment that you decide to stop participating in the study.

The entire study ends when all the participants have finished.

9. What happens after the study has ended?

Will you get the results of the study?
About 1.5 to 2 years after your participation, the investigator will inform you about the most important results of the study. Do you prefer not to know? Please tell the investigator. He/she will not tell you in that case.

10. What will be done with your data?

Are you taking part in the study? Then you also give your consent to collect, use and store your data.

What data do we store?
We store these data:
- your name
- your gender
- your address
- your date of birth
- information about your health
- (medical) information that we collect during the study

Why do we collect, use and store your data?
We collect, use and store your data to answer the questions of this study. And to be able to publish the results.

How do we protect your privacy?
To protect your privacy, we give a code to your data. We only put this code on your data. We keep the key to the code in a safe place in the coordinating centre (Haga Teaching Hospital). When we process your data, we always use only that code. Even in reports and publications about the study, nobody will be able to see that it was about you.

Who can see your data?
Some people can see your name and other personal information without a code. These are the members of the research team who visit you for the interview and call you for the questionnaires, and the people who are checking whether the investigators are carrying out the study properly and reliably. These persons can access your data:

- The researchers of the Haga Teaching Hospital that visit you for the interview or call you for the questionnaires, and if necessary request additional information from the general practitioner or specialist in elderly care medicine.
- An auditor who works for the Haga Teaching Hospital.
- National supervisory authorities (for example the Health and Youth Inspectorate).

These people will keep your information confidential. We ask you to give permission for this access.

For how long do we store your data?
We store your data in the Haga Teaching Hospital for 15 years. Your data will be stored for 15 years in order to be able to make new assessments related to this study in the course of this study.

Can we use your data for other research?
Your collected data may also be important for other medical research on elderly with a lower respiratory infection or pneumonia. For this purpose, your data will be stored in the Haga Teaching Hospital for 15 years. Please indicate in the consent form whether you agree with this. Do you not want to give your consent? Then you can still take part in this study. You get the same care.

What happens if there are coincidental findings?
It is possible that during the study we discover something that is not directly relevant to the study but is important to your health. In that case, the investigator will contact your general practitioner. You will then discuss what needs to be done with your general practitioner. With the form, you give consent to inform your doctor or specialist.

Can you take back your consent for the use of your data?
You can take back your consent for the use of your data at any time. This applies both to the use in this study and to the use in other medical research. But please note: if you take back your consent, and the investigators have already collected data for research, they are still allowed to use this information.

We can send your coded data to other countries inside and outside the European Union
After the publication of this study, we can send the dataset with coded data (including your data) to other researchers in countries within the European Union and outside the European Union upon reasonable request. The privacy rules of the European Union do not apply in countries outside the European Union. We ask for your consent for this.

Do you want to know more about your privacy?

- Do you want to know more about your rights when processing personal data? Visit www.autoriteitpersoonsgegevens.nl.

- Do you have questions about your rights? Or do you have a complaint about the processing of your personal data? Please contact the person who is responsible for processing your personal data. For the present, this is:
    - The Haga Teaching Hospital. See **Appendix A** for contact details & website.
- If you have any complaints about the processing of your personal data, we recommend that you first discuss them with the research team. For more information about privacy, view the privacy statement on the Haga Teaching Hospital website: see **Appendix A**. You can also contact the Data Protection Officer of the Haga Teaching Hospital. Or you can submit a complaint to the Data Protection Authority.

Where can you find more information about the study?
You can find more information about the study on the following website: ISRCTN registry (www.isrctn.com). After the study, the website may show a summary of the results of this study. You can find the study by searching for: ISRCTN68786381.

11. Will you receive compensation if you participate in the study?

The additional visit and phone calls for the study will not cost you anything. You will not receive any compensation if you participate in this study.

12. Are you insured during the study?

You are not additionally insured for this study. Because taking part in the study has no additional risks. That is why the Medical Ethics Review Committee Leiden The Hague Delft does not oblige the Haga Teaching Hospital to take out additional insurance.

13. We will inform your general practitioner

The investigator will call your general practitioner to let him/her know you are participating in the study. If you are going to receive hospital-at-home treatment from the ED, the attending physician on the ED will contact your general practitioner. This is for your own safety. If you receive hospital-at-home treatment started or are admitted to a nursing home via your general practitioner, we can contact your general practitioner for example about your medical history and your current medication.

14. Do you have any questions?

You can ask questions about the study to the research team. Would you like to get advice from someone who is independent from the study? Then contact dr. Iwan A. Meynaar. He knows a lot about the study, but is not a part of this study.

Do you have a complaint? Discuss it with the investigator or the doctor who is treating you. If you prefer not to do so, please contact the complaints officer. **Appendix A** tells you where to find this.

15. How do you give consent for the study?

You can first think carefully about this study. Then you tell the investigator if you understand the information and if you want to take part or not. If you want to take part, the next work day a member of the research team will visit you on location (at home, at the nursing home or at the hospital) to who you can ask additional questions, he/she will ask you to fill in the consent form that you can find with this information sheet. You and the investigator will both get a signed version of this consent form.

Thank you for your attention.

16. Appendices to this information

A. Contact details for the Haga Teaching Hospital
B. Consent form study participant (patient)
C. Consent form representative study participant (patient)

Appendix A: Contact details for the Haga Teaching Hospital

Contact details involved researchers

Principal investigator

Cees van Nieuwkoop, MD, PhD, Internal Medicine, Haga Teaching Hospital
Els Borst-Eilersplein 275, 2545AA, The Hague
E-mail address for contacting: c.vannieuwkoop@hagaziekenhuis.nl
Phone number for contacting: +31702105561

Research doctors

Rick Roos, MD, Internal Medicine, Haga Teaching Hospital
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Rianne M.C. Pepping, MD, Internal Medicine, Haga Teaching Hospital
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Research nurse

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Independent expert

Iwan A. Meynaar, MD, PhD, Intensive Care, Haga Teaching Hospital
Els Borst-Eilersplein 275, 2545AA, The Hague
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Phone number for contacting: +31702104306

Complaints

In the event of complaints, you can contact the complaints officer of the Haga Teaching Hospital by email: klachten.suggesties@hagaziekenhuis.nl. You can also contact the complaints officer by telephone during office hours on Monday to Friday (+31702102547 or +31702101814).

Institution's Data Protection Officer

If you have any questions about the protection of your privacy, you can contact the Data Protection Officer (DPO) of the Haga Teaching Hospital at fg@hagaziekenhuis.nl. You can also contact the DPO by telephone during office hours on Monday to Friday on +31702100000 with the question whether you can be put through to the DPO.

For more information about your rights

Contact details Haga Teaching Hospital

Els Borst-Eilersplein 275, 2545AA, The Hague

Central telephone number: +31702100000

Website: https://www.hagaziekenhuis.nl/privacy-en-disclaimer/privacy/

Appendix B: Consent form study participant (patient)

Belonging to The Hague RTI Care Bridge

- I have read the information sheet. I was able to ask questions. My questions have been answered well enough. I had enough time to decide if I wanted to take part.
- I know that taking part is voluntary. I also know that at any time I can decide not to take part in the study. Or to stop taking part. I do not have to explain why.
- I give the investigators consent to inform my general practitioner that I am taking part in this study.
- I give the investigators consent to request information from my general practitioner or treating physician about my medical history, medication and test results. Physicians are only allowed to share information when you have given consent for it.
- I give the investigators consent to give my general practitioner information about accidental discoveries made during the study that are important for my health.
- I give the investigators consent to collect and use my data. The investigators only do this to answer the question of this study.
- I give consent to store a (copy) of my signed consent form in the Haga Teaching Hospital.
- I know that some people will be able to see all of my data to review the study. These people are mentioned in this information sheet. I give consent to let them see my data for this review.
- I know that after publication of this study the dataset of this study, including my coded data, can be sent to other researchers in countries within and outside the European Union upon reasonable request. The privacy rules of the European Union do not apply in countries outside the European Union. I consent to this.
- I give consent to the Haga Teaching Hospital to use my contact details for the study visit, the interview and for taking the questionnaires by phone.
  Name:_____
  Address:_____
  Zip code:_____
  Place:_____
  Phone number:_____

- Please tick yes or no in the table below.

I give consent to store my data to use for other research, as stated in the information sheet.	Yes ☐	No ☐
I give consent to be approached for an in-depth interview about my experiences with the received care.	Yes ☐	No ☐
I give consent to ask me after this study if I want to participate in a follow-up study.	Yes ☐	No ☐
I give consent to inform me about the study results.	Yes ☐	No ☐

- I want to take part in this study.

My name is (study participant): ……..
Signature: ..... Date: __ / __ / __

I declare that I have fully informed this subject about the study mentioned.

If any information becomes known during the study that could influence the subject's consent, I will let this subject know in good time.

Investigator name (or their representative): .....
Signature:..... Date: __ / __ / __

The study subject will receive a complete information sheet, together with a signed version of the consent form.

Appendix C: Consent form representative study participant (patient)

Belonging to The Hague RTI Care Bridge

I have been asked to give consent for the following person to take part in this medical study:

Subject's name:…….. Day of birth: __ / __ / __

- I have read the information sheet for subjects/representatives. I was able to ask questions. My questions have been answered well enough. I had enough time to decide if I want this person to take part.
- I know that taking part is voluntary. I also know that I can decide at any time that this person will not take part after all. I do not have to explain why.
- I give the investigators consent to inform the general practitioner who treats this person that this person is taking part in this study.
- I give the investigators consent to request information from the general practitioner treating this person about his/her medical history, medication and test results.
- I give the investigators consent to inform this person's general practitioner about accidental discoveries made during the study that are important for this person's health.
- I give consent to collect and use this person's data. The investigators will only do this to answer the question of this study.
- I give consent to store a (copy) of my signed consent form in the Haga Teaching Hospital.
- I know that some people will be able to see all of this person's data to review the study. These people are mentioned in this information sheet. I give consent to let these people see this person's data for this review.
- I know that after publication of this study the dataset of this study, including the coded data of this person, can be sent to other researchers in countries within and outside the European Union upon reasonable request. The privacy rules of the European Union do not apply in countries outside the European Union. I consent to this.
- I give consent to the Haga Teaching Hospital to use the contact details of this person for the study visit, the interview and for taking the questionnaires by phone.
  Name:_____
  Address:_____
  Zip code:_____
  Place:_____
  Phone number:_____

- Please tick yes or no in the table below.

I give consent to have this person's data stored for use in other study, as stated in the information sheet.	Yes ☐	No ☐
I give consent that this person will be approached for an in-depth interview about his/her experiences with the received care	Yes ☐	No ☐
I give consent to ask this person after this study if he/she wants to participate in a follow-up study.	Yes ☐	No ☐
I give consent to inform this person about the study results.	Yes ☐	No ☐

- I agree that this person takes part in this study.

Name of legal representative:.....
Relationship to the subject:.....
Signature:..... Date: __ / __ / __

I declare that I have fully informed the person(s) mentioned above about the said study.

If any information becomes known during the study that could influence the representative's consent, I will let them know in good time.

Investigator name (or their representative):.....
Signature:..... Date: __ / __ / __

The representative will receive a complete information sheet, together with a signed version of the consent form.