

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 you are the treating physician of a patient who is diagnosed 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, friends or colleagues 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 needs approximately 100 treating physicians of participants in The Hague RTI Care Bridge, ideally 50 treating physicians of patients treated at home or in a nursing home and 50 treating physicians of patients treated in the hospital. The informal caregivers of all subjects will also be approached for study 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?

An elder patient is diagnosed 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, delirium, falls and conditional decline.

In many cases, elderly are hospitalized because the protocols between the involved care partners (for example: general practitioners, hospitals, nursing homes and home care organisations) are 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 attending physicians.

3. What is the background of the study?

In many cases, elderly are hospitalised because the protocols between the involved regional care partners (for example general practitioners, hospitals, nursing homes and home care organisations) are 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 have been 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 (and complications) 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 treating physician participating in the study? In that case, the study will take you approximately 1 month in total. The study will take around 12 months for your patient.

Step 1: Are you eligible to take part?

First, we want to know if your patient is eligible to take part in the study. If your patient is eligible to participate in the study, you as treating physician are also eligible to take part.

Your patient is eligible to take part in the study if he/she is 65 years or older and the general practitioner or attending physician at the ED has diagnosed him/her with an acute lower respiratory tract infection or pneumonia for which he/she does not need more than 5 litres of extra oxygen.,

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

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

Step 2: Study and measurements

It is for you as treating physician not necessary to visit the hospital more often for the study or measurements. You will be contacted by phone once for this study. The treating physicians of the first ten patients who receive the hospital-at-home treatment through the care pathway will also be asked whether they voluntarily agree to an interview about their experiences as a treating physician with the hospital-at-home treatment.

1st Contact moment: 30 days after the start of participation

A member of the research team (Haga Teaching Hospital) will contact you by phone to complete a questionnaire (approximately 5 minutes), with a particular focus on your satisfaction with the provided care from the perspective of the treating physician.

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

If you have given consent, a member of the research team (Haga Teaching Hospital) will visit you at your general practice for an in-depth interview (approximately 30 minutes) which will mainly focus on your experiences with the hospital-at-home treatment that you gave your patient. If you give consent for this, the interview will be recorded with a recorder. The information from these interviews is used to adjust the care pathway if necessary.

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 no longer want to take part in the study.
 - Your telephone number or 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 questionnaire and the interview.

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

You yourself do not benefit from taking part in this study. But if you take part you will help the investigators to get more insight into the experiences of treating physicians with treating patients with an acute moderate-severe lower respiratory infection or pneumonia at home, in a nursing home or in the hospital.

Taking part in the study can have this con:

- Study participation will cost you extra time (minimum 5 minutes, maximum 35 minutes).

You do not wish to participate in the study?

It is up to you to decide if you as treating physician wish to participate in the study. You do not wish to participate? In that case, this will have no further consequences for the treatment of your patient.

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 month after you started participating.
- 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.
- 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 (general practice/nursing home/hospital)
- your year of birth
- 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 questionnaire, 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 questionnaire.
- 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. They 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 the experiences with care in different locations (home, nursing home, hospital). 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.

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 optional visit for the interview and the phone call for the questionnaire will cost you nothing. 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 not inform your general practitioner

The investigator will not inform your general practitioner that you are taking part in the study, as participation in the study does not entail any health risks for you as a treating physician.

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, 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 (physician)

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

Els Borst-Eilersplein 275, 2545AA, The Hague

E-mail address for contacting: r.roos@hagaziekenhuis.nl

Phone number for contacting: +31702105579

Rianne M.C. Pepping, MD, Internal Medicine, Haga Teaching Hospital

Els Borst-Eilersplein 275, 2545AA, The Hague

E-mail address for contacting: r.pepping@hagaziekenhuis.nl

Phone number for contacting: +31708009047

Research nurse

Annemarie Donker, research coordinator, Internal Medicine, Haga Teaching Hospital

Els Borst-Eilersplein 275, 2545AA, The Hague

E-mail address for contacting: a.donker@hagaziekenhuis.nl

Phone number for contacting: +31702103683

Independent expert

Iwan A. Meynaar, MD, PhD, Intensive Care, Haga Teaching Hospital

Els Borst-Eilersplein 275, 2545AA, The Hague

E-mail address for contacting: i.meynaar@hagaziekenhuis.nl

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 (physician)

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 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 interview and for taking the questionnaire by telephone.

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 provided 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.