Subject Information for Participation in Medical Scientific Research

“A polyethylene socket or a combination of polyethylene and metal in stemless anatomic shoulder prostheses”

Hybrid versus polyethylene glenoid components in stemless anatomic shoulder prostheses: a multicenter, prospective, non-inferiority randomized study

Introduction

Dear Sir/Madam,

With this information letter, we would like to ask whether you would be willing to participate in medical scientific research. Participation is voluntary. You will soon undergo shoulder surgery in which a total shoulder prosthesis will be implanted. Your treating orthopedic surgeon has indicated that you are eligible to participate in this medical scientific study.

This letter explains what the study is about, what participation means for you, and what the advantages and disadvantages are. It is a lot of information. Please read it carefully and decide whether you would like to participate. If you wish to participate, you can complete the form found in Appendix C.

Ask your questions

You can make your decision based on the information in this letter. In addition, we advise you to do the following:

- Ask questions to the researcher who gave you this information.
- Discuss this study with your partner, family, or friends.
- Ask questions to the independent expert. For contact details, see Appendix A.
- Read the information on the Dutch government website about medical research involving human subject

1. General information

The Department of Orthopedics of Spaarne Gasthuis has set up this study. Financial support has been provided by Limacorporate S.p.A. (Villanova, Udine, Italy). Hereafter, Spaarne Gasthuis will be referred to as the Sponsor. Researchers will carry out the study in several hospitals. Limacorporate pays for this study. With this information letter, we would like to provide you with more information about the study.

Participants in medical scientific research are often referred to as subjects. Both patients and healthy individuals can be subjects. For this study, 94 subjects from the participating hospitals are needed. This study will be conducted at Spaarne Gasthuis (Hoofddorp), Isala Hospital (Zwolle), and Albert Schweitzer Hospital (Dordrecht).

The Medical Ethics Review Committee of Amsterdam UMC has approved this study.

2. What is the purpose of the study?

In an anatomic shoulder prosthesis procedure, both the head and the socket of the joint are replaced with a new head and socket. The aim of this study is to compare two different types of glenoid components. The metal head used is the same for everyone. The difference between the two socket types lies in the material used. The “standard” material is a plastic socket (polyethylene) whose plastic pegs are fixed into the bone with cement. The other socket is made of plastic and is fixed with a central metal peg (hybrid). The aim of this study is to determine whether the socket made of metal and plastic provides at least equally good results as a socket made entirely of plastic.

In the short term, there is no disadvantage that you are expected to experience from either method. A possible difference may be the duration of fixation in the long term. The purpose of this study is to investigate this difference.

The model glenoid component being studied is the **SMR TT Hybrid Glenoid** (Limacorporate S.p.A., Villanova, Udine, Italy) (see Figure 1). This product is compared with the **SMR Polyethylene Glenoid** (Limacorporate S.p.A., Villanova, Udine, Italy) (see Figure 2).

Fig. 1: Hybrid glenoid component

Fig. 2: Polyethylene glenoid

3. What is the background of the study?

The shoulder joint is formed by the shoulder blade and the head of the upper arm bone. The shoulder blade has a small socket into which the head of the upper arm bone fits. A total shoulder prosthesis therefore consists of two parts: one part is placed in the shoulder blade and the other in the upper arm bone. The components of the shoulder prosthesis are available in different sizes and materials, with many possible combinations. In this way, each patient receives a “custom-made” prosthesis. This operation is recommended when the cartilage of the socket and the head of the shoulder is worn out. This condition is called osteoarthritis. Replacing the head and the socket is a solution for your shoulder problem if you experience too much pain and pain medication together with exercises has too little effect. The ideal material for the shoulder head is metal (cobalt-chromium), and for the socket a low-wear plastic (polyethylene). In the long term, wear or loosening of the prosthesis may occur in your operated shoulder. The greatest risk of this is in the glenoid component. The hybrid glenoid component (plastic and metal) was developed to reduce this. In this study, the new glenoid component is compared with the component that is currently most commonly used, namely the polyethylene-only (plastic) component

4. How will the study be conducted?

Patients who are placed on the waiting list for a stemless anatomic total shoulder prosthesis at, among others, Spaarne Gasthuis Hoofddorp may participate in this study. In the Netherlands, 94 people will participate in this study, with subjects equally divided into two groups.

Subjects in group 1 will receive the cemented all-polyethylene glenoid component, and subjects in group 2 will receive the hybrid glenoid component. Assignment to a group will be determined by randomization. The orthopedic surgeon and the research staff have no influence whatsoever on this randomization.

The study was designed by a research team at Spaarne Gasthuis under the supervision of Dr. A. van Noort. The study is being carried out in collaboration with several hospitals in the Netherlands. Your participation in the study will last a total of 10 years. The study as a whole will last approximately 13 years.

The two different types of glenoid components being compared in this study are both well-known and effective treatment methods with which there has already been long-term experience. All procedures related to the operation are carried out according to the standard care pathway of Spaarne Gasthuis, including preoperative screening and discharge procedures. This is therefore no different from patients who do not participate in the study.

Before the operation and several times afterward (6 weeks, 3 months, 1 year, 2 years, 5 years, 7 years, and 10 years), you will visit the hospital for an outpatient follow-up appointment with the orthopedic surgeon, including X-rays. The appointments at 6 months (telephone only), 2 years, and 7 years after the operation are extra for this study.

At each visit, you will also be seen by the research nurse or physician-researcher. In addition, you will be asked to complete several questionnaires about your health and satisfaction before and after the operation. Completing the questionnaires takes about 15 minutes each time.

Six months after the operation, you will be contacted by telephone by the research nurse or physician-researcher for a number of questions/questionnaires.

If you participate in the study, the following will therefore be expected of you in addition:

- Outpatient follow-up at 2 and 7 years after surgery
- Telephone follow-up at 6 months after surgery
- Completion of questionnaires before and after surgery

In Appendix B you will find an overview of the study visits and the purposes for which we will invite you to the outpatient clinic.

5. What agreements do we make with you?

We would like the study to proceed properly. Therefore, we make the following agreements with you:

- You attend every appointment.
- You contact the researcher in the following situations:
    - When you no longer wish to participate in the study.
    - Your telephone number, address, or email address changes.

6. What side effects, adverse effects, or inconveniences might you experience?

Apart from the normal risks associated with the implantation of a shoulder prosthesis, there are no additional risks associated with participation. The follow-up visits (including X-rays) at 2 and 7 years after the operation are additional for this study. The total amount of extra radiation you receive as a result falls within the limits for scientific research and is classified as “minimal.” The total radiation dose used in the context of the study was calculated by the clinical physicist, Ir. Hugo Spruijt. In the standard situation, a total of 1 CT scan and 6 shoulder X-rays are performed. In the context of the study, 2 additional shoulder X-rays will be taken at 2 and 7 years after the operation. For the radiation calculation, the international calculator was used (*Radiation risks from medical x-ray examinations as a function of the age and sex of the patient*, BF Wall et al., HPA-CRCE-028 (2011), www.hpa.org.uk). The calculation shows that a maximum of 32 microSievert may be assumed per shoulder X-ray. This means that participation in the study results in an additional radiation exposure of 64 microSievert over a period of 10 years. This amount is negligible and can be compared with the background radiation to which every person is exposed over a period of 10 days.

For safety reasons, women who are pregnant or wish to become pregnant will not be asked to participate in the study. If pregnancy nevertheless occurs during the study, we are obliged to follow the pregnancy until after birth. Under no circumstances will X-rays be taken during pregnancy.

7. What are the advantages and disadvantages of participating in the study?

You will not personally benefit from participating in this study. However, your participation will help researchers gain more insight into the functioning of a stemless total shoulder prosthesis.

Participating in the study may have the following disadvantages or consequences:

Participation takes extra time.

You must comply with the appointments associated with the study.

Do you prefer not to participate?

A total shoulder prosthesis is the standard treatment for a worn shoulder. You decide for yourself whether to participate in the study. If you do not wish to participate, you do not have to be randomized to one of the two operations. In consultation with your treating orthopedic surgeon, you may then decide which type of operation, and therefore which type of glenoid component, you prefer.

8. When does the study stop?

The researcher will inform you if new information about the study becomes available that is important for you. The researcher will then ask whether you wish to continue participating.

In the following situations, the study will stop for you:

- All study procedures according to the schedule have been completed.
- The entire study has ended.
- You decide yourself to stop participating. You may do so at any time. Please inform the researcher immediately. You do not need to explain why you are stopping. You will then return to receiving regular treatment for your shoulder. The researcher may still invite you for a follow-up visit, or may arrange one or more additional checks for your safety.
- The researcher considers it better for you to stop. The researcher will still invite you for a follow-up visit.
- One of the following authorities decides that the study must stop: Limacorporate S.p.A. (Villanova, Udine, Italy), the government, or the medical ethics committee that reviews the study.

What happens if you stop participating in the study?

The researchers will use the data collected up to the moment you stop.\

9. What happens after the study?

The researcher will discuss with you what other medical care you will receive.

Will you receive the results of the study?

Approximately two years after the study has been completed, the researcher will inform you of the main outcomes of the study.

10. What do we do with your data?

If you participate in the study, you also give permission for your data to be collected, used, and stored.

What data do we store?

- Your sex
- Your address
- Your date of birth
- Information about your health
- Medical data that we collect during the study

Why do we collect, use, and store your data?

We collect, use, and store your data in order to answer the research questions of this study and to be able to publish the results. Data may be used by the Sponsor and the company that assists the Sponsor in carrying out the study or analyzing the research data. In this case, Spaarne Gasthuis is the Sponsor and the company involved is Limacorporate S.p.A. (Villanova, Udine, Italy). Only coded, anonymized data will be shared; your name will never be shared.

How do we protect your privacy?

To protect your privacy, we assign a code to your data. Only this code is placed on all your data. The key to the code is kept in a secure location in the hospital. Whenever we process your data, we use only that code. No one will be able to trace the data back to you in reports or publications about the study.

Who may see your data?

Some individuals may still be able to view your name and other personal data without the code. This may include data specifically collected for this study, as well as data from your medical records. These are people who check whether the researchers are conducting the study properly and reliably. These persons may have access to your data:

- A monitor hired by the Sponsor, or a monitor working for the Sponsor
- National and international supervisory authorities

These persons are obliged to keep your data confidential. We ask your permission for access by these persons. The Health and Youth Care Inspectorate may inspect your data without your permission.

How long do we keep your data?

We keep your data for 15 years at the research center. Your collected data may also be important for other scientific research or for the further development of the anatomic shoulder prosthesis. For that purpose, your data will also be stored for 15 years at the research center. In the consent form, you can indicate whether you agree to this. If you do not consent, you may still participate in this study. You will receive the same care.

What happens in the event of unexpected findings?

During the study, we may incidentally discover something that is not directly relevant to the study but may be relevant to your health. The researcher will then contact your general practitioner or specialist. You will discuss with your general practitioner or specialist what should be done. The costs of this fall under your own health insurance. By signing the form, you consent to informing your general practitioner or specialist.

Can you withdraw your consent for the use of your data?

You may withdraw your consent for the use of your data at any time. Please tell the researcher if you wish to do so. This applies to the use of your data in this study and in other research. Please note: if you withdraw your consent after researchers have already collected data for a study, they may still use the data already collected.

Would you like to know more about your privacy?

- If you would like to know more about your rights regarding the processing of personal data, please visit the website of the Dutch Data Protection Authority.
- If you have questions about your rights, or if you have a complaint about the processing of your personal data, please contact the party responsible for processing your personal data. For this study, that is Spaarne Gasthuis.
- If you would like to know more about Limacorporate S.p.A., Villanova, Udine, Italy, and Spaarne Gasthuis, see Appendix A for contact details and website information.
- If you have complaints about the processing of your personal data, we recommend that you first discuss them with the research team. You may also contact the Data Protection Officer of Spaarne Gasthuis or submit a complaint to the Dutch Data Protection Authority.

Where can you find more information about the study?

More information about the study can be found on ClinicalTrials.gov. After the study has ended, the website may show a summary of the results of this study. You can find the study by searching for: "Hybrid versus poly-ethylene glenoid in stemless anatomical shoulder arthroplasty."

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

The additional tests required for the study will not cost you anything. You will also not receive compensation for participating in this study. However, you will be reimbursed for your additional travel expenses. This applies to the extra follow-up visits at 2 and 7 years after surgery.

12. Are you insured during the study?

You are not additionally insured for this study because participation does not involve extra risks. Therefore, the Medical Ethics Review Committee of Amsterdam UMC has determined that Spaarne Gasthuis does not need to arrange additional insurance.

13. We will inform your general practitioner

The researcher will send your general practitioner a digital letter to inform them that you are participating in the study. This is for your own safety.

14. Do you have any questions?

If you have questions about the study, you may ask the research team. If you would like advice from someone who has no interest in the study, please contact the independent physician; see Appendix A for contact details. This person knows a great deal about the study but is not involved in it.

If you have a complaint, please discuss it with the researcher or the physician treating you. If you would rather not do so, please contact the complaints committee of Spaarne Gasthuis. Appendix A states how to reach them.

15. How do you give consent for the study?

You may first take time to think about the study. Then you tell the researcher whether you understand the information and whether or not you wish to participate. If you wish to

participate, complete the consent form included with this information letter. You and the researcher will each receive a signed copy of this consent form.

Thank you for your time.

16. Appendices to this information

A. Contact details

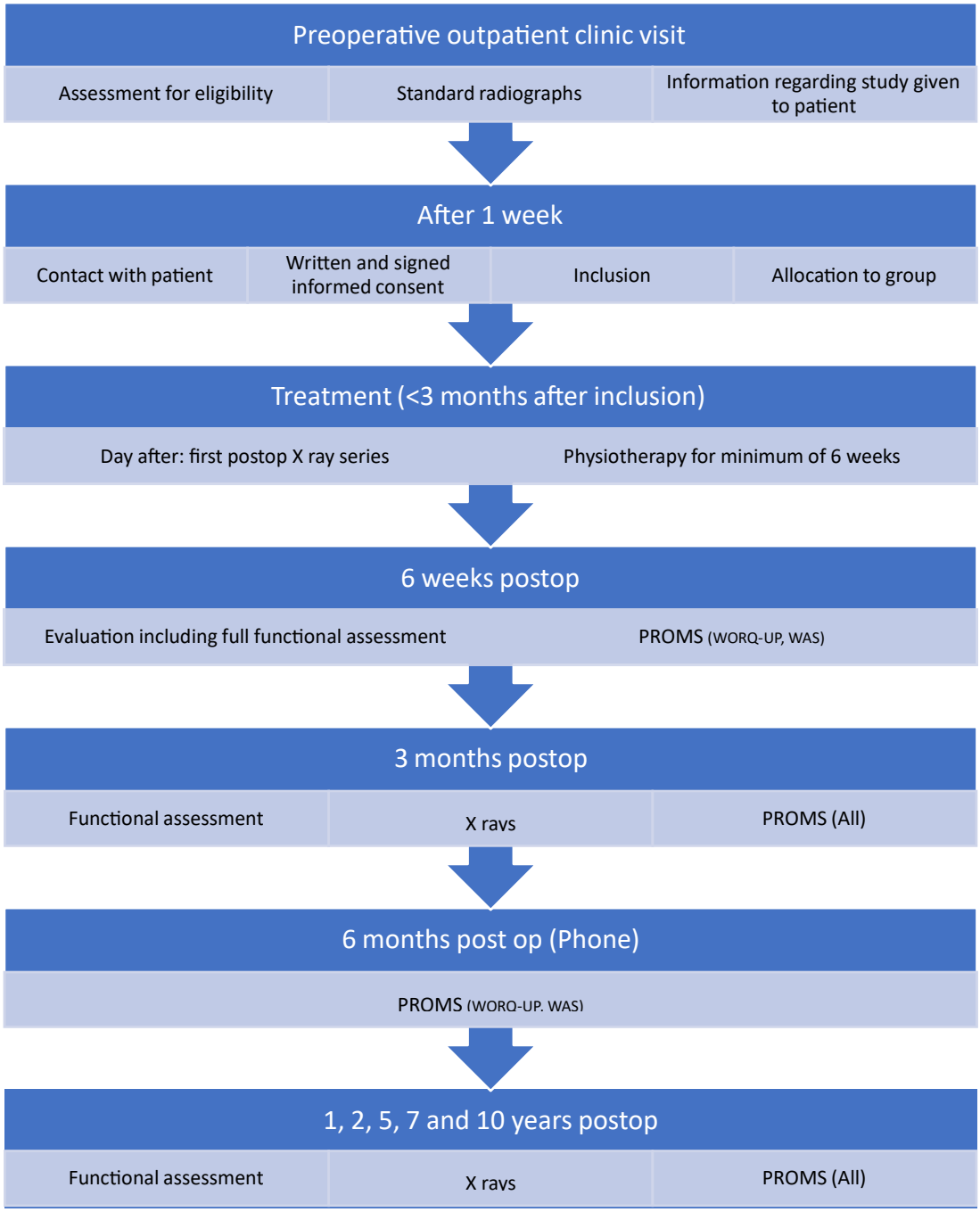
B. Schedule of study procedures

C. Consent form

Appendix A: Contact details for Spaarne Gasthuis

Role	**Details**
Principal investigator	Dr. A. van Noort, orthopedic surgeon Email: avannoort@spaarnegasthuis.nl Tel. (023) 224 01 30 (orthopedic outpatient clinic)
Research coordinator	Drs. Marjolein Schager, research nurse Email: mschager@spaarnegasthuis.nl Available: Mon-Tue-Wed-Thu Tel. 023 - 224 16 73
Independent physician	Dr. J. van Aken, rheumatologist Email: jvanaken@spaarnegasthuis.nl Tel. 023 - 224 01 70 (rheumatology outpatient clinic)
Complaints Committee, Spaarne Gasthuis (coordinating center)	Via the complaints form on the website Email: klachten@spaarnegasthuis.nl Telephone via the complaints officer: 023 - 224 21 30 In writing: Spaarne Gasthuis, Attn. Complaints Department, Reply Number 900, 2000 VB Haarlem
Data Protection Officer of Spaarne Gasthuis (coordinating center)	Email: fg@spaarnegasthuis.nl Tel. 023 - 224 21 81
External funding	Limacorporate S.p.A., Villanova, Udine, Italy

Appendix B: Schedule of study procedures



The X-rays at 1, 5 and 10 years are part of standard care. The X-rays at 2 and 7 years are part of the study.

Signed informed consent = consent form
Randomization = allocation by chance
PROMs = questionnaires

Appendix C: Subject consent form

"A polyethylene socket or a combination of polyethylene and metal in stemless anatomic shoulder prostheses"

- I have read the information letter. I was also able to ask questions. My questions were answered satisfactorily. I had enough time to decide whether to participate.
- I understand that participation is voluntary. I also understand that I may decide at any time not to participate in the study after all, or to stop participating. I do not need to state why I wish to stop.
- I give the researcher permission to inform my general practitioner that I am participating in this study.
- I give the researcher permission to provide my general practitioner or specialist with information about unexpected findings from the study that are relevant to my health.
- I understand that, for the purpose of monitoring the study, certain people may inspect all of my data. These people are listed in this information letter. I give these people permission to inspect my data for this monitoring.

Please continue to the next page.

Please tick yes or no in the table below:

Statement	Yes	No
I consent to my data being stored for use in other research, as described in the information letter.	☐	☐
I consent to possibly being asked after this study whether I would like to participate in a follow-up study.	☐	☐
I give the researchers permission to tell me after the study which treatment I received / which group I was in.	☐	☐

I want to participate in this study.

My name is (subject): .....

Signature: ..... Date: ___ / ___ / ___

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

If information becomes available during the study that may influence the subject's consent, I will inform this subject in time.

Name of researcher (or representative): .....

Signature: ..... Date: ___ / ___ / ___

Additional information was provided by:

Name: .....

Position: .....

Signature: ..... Date: ___ / ___ / ___

The subject will receive a complete information letter together with a signed copy of the consent form.