Subject information for participation in medical research

Study on the treatment of thumb base osteoarthritis and hand therapy

Introduction

Dear Sir/Madam,

With this letter, we would like to ask you to take part in a medical study. Participation is voluntary. Your written permission is required to participate. You have received this letter because your treating hand surgeon has decided to refer you for hand therapy. Before you decide whether you want to participate in this study, you will receive an explanation of what the study entails. Read this information carefully and ask the researcher for an explanation if you have any questions. You can also ask the independent expert named at the end of this letter for additional information. You can also talk about it with your partner, friends or family. Further information about participating in such a study can be found on the website of the national government: https://www.government.nl/topics/medical-research .

1. General information

This research was set up by MC Rotterdam and is being carried out by doctors, therapists and researchers in various treatment centers for hand and wrist conditions. For this study, 532 participants from the Netherlands are needed. The medical ethics review committee of the Erasmus MC has approved this research. General information about the assessment of research can be found on the website of the national government.

2. Aim of the study

The aim of this study is to determine whether there are better outcomes for patients with thumb base osteoarthritis who, in addition to using an orthosis, also receive exercise therapy compared to patients using only an orthosis. In addition, we want to know how often surgery is needed after hand therapy. It would be better if patients with this condition needed surgery less often, because surgery does not always lead to good outcomes and recovery may take a very long time. For example, most patients are unable to work for about 15 weeks after surgery.

3. Background of the study

People with thumb base osteoarthritis of the thumb base are currently first offered hand therapy, consisting of an orthosis, whether or not supplemented with exercise therapy. However, there is a lot of variation in the treatment that is given. Not everyone with thumb base osteoarthritis will receive exercise therapy in addition to an orthosis. In addition, the optimal content of exercise therapy is still unknown.

4. What it means to participate

Your participation will take about 12 weeks. Participants in this study will receive only an orthosis or a combination of an orthosis and exercise therapy. The treatment of receiving the orthosis consists of two visits; a visit for a custom made orthosis and instructions on how and when to wear it, and a visit to check the orthosis. An orthosis is also made for the combination treatment consisting of using an orthosis in combination with exercise therapy. Exercise therapy consists of weekly physiotherapy sessions of 25-30 minutes and exercises to do at home. In the physiotherapy sessions, information is given, functional exercises for the thumb are given and homework exercises are given, which must be performed at home a number of times a day for ±5 minutes. The exercises consist of coordination, flexibility and strength exercises.

Half of all participants in this study will receive only an orthosis, and the other half will also receive exercise therapy in addition to the orthosis. To keep the distribution as fair as possible, a draw determines who will receive only the orthosis and who will also receive exercise therapy. That draw is called randomization. Your attending surgeon and the researchers have no influence on the result of the draw. Therefore, you cannot indicate which program you want to follow in advance. The chance that you will be in one of the two groups is 50%. If u decide not to participate in this study, you will receive standard care.
If you participate, you will be measured at five different times: during you first visit, after 6 weeks, after 3 months, after 6 months, and after 1 year. The measurement look similar at every measurement moment. To some extent, these measurements are already performed as part of your treatment, even if you do not participate in this study. This is, for example, taking X-rays, determining the degree to which you experience pain and limitations in hand function. We also ask you to complete a number of additional questionnaires. It is estimated that it will take a maximum of 15 minutes to answer these additional questionnaires and to perform these additional measurements. So in total it takes you 5 times a maximum of 15 minutes extra time when you participate in this study. We will also measure the strength and flexibility of the thumb and hand. This will happen during your first visit, after 6 weeks, after 3 months as part of your treatment, but you will need to come back for this after 6 months and after 1 year. These 2 additional visits will take up to 10 minutes of your time. The first test is a test to measure the muscle strength in your hand. You will then be asked to squeeze a

measuring tool as forcefully as possible and to apply pressure between your thumb and your fingers as forcefully as possible. During the second test, the aim is to determine how flexible your thumb is. It will therefore be determined with the help of a protractor and caliper how far you can move the thumb.

In addition to the things mentioned above, we are looking for patients who want to do something extra. We are looking for participants of this research who also want to share their experiences with the research with us. If you participate in this study, it is not mandatory to also participate in the panel. If you want to participate in this panel, we ask you to participate twice in a group discussion. If you participate, you will receive a travel allowance and a gift voucher worth €15.

5. What is expected of you

In order for the study to run smoothly, it is important that you adhere to the following agreements.

The agreements are that you:

- If applicable, do the exercises according to the explanation.
- Do not also participate in another medical scientific study that focuses on a hand or wrist disorder.
- Keep appointments for visits.

It is important that you contact the researchers:

- If you are admitted to or treated in a hospital.
- If you suddenly develop health problems.
- If you no longer wish to participate in the study.
- If your contact details change.

6. Potential risks of participating in this study

There is no risk involved in participating in this study.

7. Potential advantages and disadvantages

It is important that you carefully consider the possible advantages and disadvantages before you decide to participate. You will not directly benefit from participating in this study; despite the indications in scientific research, we are not sure whether the combination of an orthosis and exercise therapy is actually more effective than an orthosis alone. However, we expect that surgery will be required less often if exercise therapy is followed in addition of the use of an orthosis.

We strive to match the measurement moments and information as much as possible so that

you have to travel to the treatment center as less as possible.
Nevertheless, a disadvantage of participating in this study remains the time investment that we ask from you.

8. If you don't want to participate or want to stop participating in the study

You decide whether you want to participate in the study. Participation is voluntary. If you don't want to participate you will be treated for your thumb base osteoarthritis in the usual way. The researcher can tell you more about the available treatment options and their advantages and disadvantages.

Of you do participate, you can always change your mind and stop anyway, even during the study. You will then be treated in the usual way for you thumb base osteoarthritis. You don't have to say why you're stopping, but you must report immediately that you want to stop to the researcher.
The data collected up to that point will be used for the research.
If there is new information about the study that is important to you, the researcher will let you know. You will then be asked if you want to continue participating.

If the combination of an orthosis and exercise therapy does indeed lead to good results and the effects are large enough compared to the costs, then we will replace the current care with the new program for people with thumb base osteoarthritis after the study has been completed. We will inform all participants of the results at the end of the study.

9. End of the study

Your participation in this study will end if:

- All visits as described under point 4 are over.
- You choose to stop.
- The researcher thinks it's better for you to quit.
- The Erasmus MC Rotterdam, the government or the assessing medical ethics review committee, decided to stop the study.

The entire study ends when all participants are ready. After processing all the data, the researcher will inform you about the most important results of the study. If you do not want this, you can say so to the researcher. Then this information will not be shared with you.

10. Use and storage of your data

Your personal data will be used and stored for this study. This concerns data such as your name, address, date of birth and data about your health. The collection, use and storage of your data is necessary to answer the questions posed in this study and to publish the results.

We ask your permission for the use of your data. In addition, we ask for your permission to inform your general practitioner and/or treating specialist in the event of unexpected findings that are (or may be) important for your health.

Confidentiality of your data

To protect your privacy, you data is given a code. Your name and other information that can directly identify you are omitted. Data can only be traced back to you with the key of the code. The key to the code remains securely stored in the local research facility. The data sent to the sponsor (Erasmus MC) only contains the code, but not your name or other data with which you can be identified. Also in reports and publications about the study, the data cannot be traced back to you.

Access to your data for inspection

Some individuals may have access to all of your data at the study site. Also the data that can be traced back to you. This is necessary to be able to check whether the study has been carried out properly and reliably. Persons who have access to your data for inspection are: an inspector who works for Erasmus MC and national supervisory authorities (for example, the Health Care Inspectorate). They keep your details secret. We ask you to give permission for this inspection.

Data retention period

Your data must be kept for 5 years at the research location and 5 years at the sponsor.

Retention and use of data for other research

After this study, your data may also be important for other scientific research in the field of thumb base osteoarthritis and hand therapy. For this, your data will be stored for 5 years. You can indicate on the consent form whether or not you agree to this. If you do not agree to this, you still can participate in the current study.

Withdraw permission

You can always withdraw your consent for the use of your personal data. This applies to this study as well as to storage and use for future research. The collected data up to the moment you withdraw your consent will still be used in the study.

More information about your rights when processing data

For general information about your rights when processing your personal data, you can consult the website of the Dutch Data Protection Authority (Autoriteit Persoonsgegevens).

Of you have any questions about your rights, please contact the person responsible for

processing your personal data. For this study, it is Erasmus MC Rotterdam. See Appendix A for contact details.

If you have any questions of complaints about the processing of your personal data, we recommend that you first contact the research location. You can also contact the Data Protection Officer of the institution or the Dutch Data Protection Authority.

Registration of the study

Information about this study is also included in an overview of medical scientific studies, the Dutch Trial Register (www.trialregister.nl). It does not contain any data that can be traced back to you. After the study, the website may display a summary of the results of this study. You will find this study under the name “THETA study”.

11. Insurance for study participants

An insurance policy has been taken out for everyone who participates in this study. The insurance covers damage caused by the study. Not all damage is covered. In Appendix B you will find more information about the insurance and the exceptions. It also states who you can report damage to.

12. Inform General Practitioner

We always send you GP a letter or e-mail to let them know that you are participating in the study. This is for your own safety. If you do not agree with this, you cannot participate in this study.

13. No compensation for participating

You will not be paid for participating in this study. You will, however, be reimbursed for your (extra) travel costs. You will be reimbursed if you participate in the panel (see 4. What is means to participate).

The orthosis and exercise therapy are possibly (partly) paid for by your health insurance; this depends on your treatment location and insurance. Physiotherapy/ hand therapy treatments that are performed within the hospital or rehabilitation center (second- and third-line care) are reimbursed from your basic insurance. If the physiotherapy/ hand therapy takes place in a regular physiotherapy/ hand therapy practice (first line), your treatments can be reimbursed from your supplementary insurance, depending on the package you have chosen and the treatments already consumed. For more information about your physiotherapy reimbursement, we recommend that you contact your health insurer. There are no additional costs associated with this study for all participants. Participants are offered a reimbursement for their travel costs for measurements that are performed 1 year after the start of the treatment.

14. Do you have any questions?

If you have questions, please contact Dr. Robbert Wouters, Erasmus MC Rotterdam. For independent advice about participating in this study, you can contact the independent doctor: Drs. R.G.M. Timmermans. Drs. Timmermans knows a lot about the study, but has nothing to do with this study.

If you have any complaints about the study, you can discuss this with the researcher or your attending physician. Of you prefer not to do this, you can contact the complaints committee of your treatment center. All details can be found in Appendix A: Contact details.

15. Signing Informed Consent Form

When you have had sufficient reflection time, you will be asked to decide whether to participate in this study. If you give permission, we will ask you to confirm this in writing on the accompanying statement of consent. By your written consent, you indicate that you have understood the information and agree to participate. Both you and the researcher will receive a signed version of this consent form.

Thank you for your attention.

16. Appendices to this information

A. Contact details

B. Information about the insurance

C. Informed Consent Form

D. Medical scientific research. General information

Appendix A: Contact details

Coordinating researcher:
Dr. Robbert Wouters, r.wouters@erasmusmc.nl

Principal investigator Erasmus MC Rotterdam:
Dr. Ruud Selles, r.selles@erasmusmc.nl

Locally responsible researcher Erasmus MC Rotterdam – Department of Plastic and Reconstructive Surgery and Hand Surgery:
Dr. Michiel Zuidam, j.zuidam@erasmusmc.nl

Locally responsible researcher Erasmus MC Rotterdam – Department of Orthopedics:
Dr. Joost Colaris, j.colaris@erasmusmc.nl

Independent expert:
Drs. R.G.M. Timmermans, rehabilitation doctor, RTimmermans@rijndam.nl

Complaints:
Complaints Committee Erasmus MC, Phone nr. : (010) 703 31 98, also see:
https://www.erasmusmc.nl/nl-nl/patientenzorg/idee-wens-klacht

Institution's Data Protection Officer: Do you have any questions about the protection of tour privacy? Please contact the Data Protection Officer (DPO) of the Erasmus MC via e-mail functionaris.gegevensbescherming@erasmusmc.nl of by telephone +31 10 703 49 86.

For more information about your rights: Dr. Ruud Selles, Department of Rehabilitation Medicine and Department of Plastic and Reconstructive Surgery and Hand Surgery, r.selles@erasmusmc.nl

Appendix B: Information about the insurance

Erasmus MC Rotterdam has taken out insurance for everyone participating in this study. The insurance covers damage caused by participating in this study. This applies to damage during the study or within four years after the end of your participation in the study. You must have reported damage to the insurer within those four years.

The insurance does not cover all damage. At the bottom of this text it is briefly stated which damage is not covered.
These provisions are set out in the 'Decree on compulsory insurance for medical research involving humans 2015'. This decision can be found in the government's 'Wettenbank' (https://wetten.overheid.nl).

In the event of damage, you can contact the insurer directly using the information below:

The insurer of the study is:	
Name:	CNA Insurance Company Europe S.A.
Address:	Polarisavenue 140, 2134 JX Hoofddorp
Phone number:	+ 31 (0)23-3036004
E-mail:	ClaimsNetherlands@cnahardy.com
Policy number:	10220695
Contact:	Esther van Herk

The insurance provides cover of € 650.000 per participant and € 5.000.000 for the entire study and € 7.500.000 per year for all studies by the same client.

The insurance does **not** cover the following damage:

- Damage from a risk of which you have been informed in the written information. Thus does not apply if the risk is more serious than anticipated or the risk was very unlikely;
- Damage to your health that would also have occurred if you had not taken part in the study;
- Damage caused by not (fully) following directions or instructions;
- Damage to your descendants, as a result of a negative effect of the research on you or your descendants;
- Damage caused by an existing treatment method in research into existing treatment methods.

Appendix C: Informed Consent Form

Study on the treatment of thumb base osteoarthritis and hand therapy

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 this study. Or to stop taking part. I do not have to explain why.
- I give the investigator consent to inform my general practitioner that I am taking part in this study.
- I give consent to collect and use my data. The investigators only do this to answer the question of this study.
- 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 give consent to give my doctor or specialist information about accidental discoveries made during the study that (may) are important for my health.
- 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 ask me after this study if I want to participate in a follow-up study.	Yes ☐	No ☐
I give consent to be asked for participation in the panel.	Yes ☐	No ☐

- I want to take part in this study.

Name participant:

Signature: Date (dd/mm/yy): __ / __ / __

- I declare that I have fully informed this participant about the study mentioned.
- If any information becomes known during the study that could influence the participant's consent, I will let this participant know in good time.

Investigator name (or their representative):
Signature: Date (dd/mm/yy): __ / __ / __

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if applicable
Additional information was given by:
Name:
Job title:
Signature: Date (dd/mm/yy): __ / __ / __

The participant will receive a complete information sheet, together with a signed version (copy) of the consent form.

Appendix D: Medical scientific research. General information

For general information about participating in medical scientific research, please visit the website of the national government: https://www.government.nl/topics/medical-research