Patient information GRAFITI-study

Research on growth behavior of aggressive fibromatosis.

Dear Sir/Madam,

We would kindly like to ask you to participate in a medical-scientific study called the GRAFITI-study. You were recently contacted by your physician because you were diagnosed with “aggressive fibromatosis”, also known as desmoid-tumor. The purpose of this study is to provide an overview of this rare disease. In addition we will investigate a specific treatment strategy and the impact of the disease on the quality of life.

The decision to participate is made by you. In order to be able to make this decision, it is important that you know more about this study. Please read this information letter carefully. Discuss participation with your partner, friends or family. There is an independent expert to whom you can ask questions. This person is well-informed about this study.

If you have any questions after reading this information, feel free to contact your physician, the study contact person or the independent expert. Please find the contact information attached to this information letter.

1. What is the purpose of the GRAFITI-study?
Aggressive fibromatosis is a very rare type of soft tissue tumor. It is sometimes called a benign form of cancer, as this tumor is not able to spread through the body. The standard treatment used to be an operation to remove the tumor. However, the results of this sometimes invasive treatment are variable. Nowadays doctors are more reluctant in treating this disease. Instead of prompt treatment, they prefer to regularly monitor the tumor if possible. This is safe because the tumor will not spread through the body, and will sometimes even get smaller. To choose a suitable treatment, it is important to predict the behavior of the tumor. This study aims to determine the behavior of this tumor. Furthermore, the effect of the tumor on the patient’s quality of life is studied. The patient’s experience is key in that part.

2. Which treatment policy will be investigated?
In this study, we will preferably treat all patients according to a *wait-and-see policy*. This implies that the tumor will be monitored very carefully by your physician, but no medication, radiation or surgery will be used.

3. How is the study conducted?
Participation in this study means that beside the standard investigations that are used to for diagnosis, an ultrasound image from the tumor will be made. This ultrasound is used to compare further ultrasounds during this study. Researchers will collect extra data from the standard investigations.

You will be under observation for at least 5 years. Please find the schedule for checkups attached to this information letter. During each checkup, your physician will ask you some questions and will perform physical examination. In addition, an ultrasound or MRI-scan will be made in order to determine possible growth or shrinkage of the tumor. Depending on the results of these investigations, your doctor will decide if it is responsible to continue the *wait-and-see policy* or if another treatment would be preferable.

We would like to ask you to fill out a questionnaire about the quality of your life. This gives us an idea of the impact of the disease on your life. If you are no candidate for a *wait-and-see policy* or you decide on another treatment with your doctor, we would still like to ask you to fill out the questionnaire.

4. What will be expected from you?
During participation in the study, we will ask you to attend the checkups and fill out the questionnaires when asked. There are no limitations because of this study. If you use medications at this moment, you can continue these. Oral anticonception (birth control pills) is also a medication, and it is important that you inform your doctor when you use these. If you are planning to get pregnant during the study, it is wise to discuss this with your doctor. This is not a limitation for the study, but it can affect your tumor.

5. What is different compared to the general treatment policies?
At the moment, there is no standard treatment policy. The doctor decides together with other experts, which policy is best for each patient. More and more experts advise the *wait-and-see policy*, if possible.

6. Which other treatment policies are available?
There are several active treatment policies available, such as medication, chemotherapy, radiation and surgery. However, it depends on the tumor which one fits best. Your doctor will inform you about the other treatment policies that are suitable for you.

7. Which adverse effects could be expected?
The *wait-and-see policy* has no adverse effects.

8. What are the advantages and disadvantages of participation in this study?
You can benefit from participation in this study. It is possible that during the *wait-and-see policy* the tumor stabilizes or even gets smaller spontaneously. When this happens, you do not have to undergo active treatment.
Possible disadvantages of participation are the questionnaires that have to be filled out and the repeated questions and the investigations that are necessary to objectify any changes in your health. There is a chance that the tumor will grow, which might make it more difficult to treat. However, the checkups are designed in such a way that growth will be detected quickly and active treatment can be started immediately if needed.

9. What happens when you do not wish to participate in this study?
Participation in this study is completely voluntarily. If you refuse participation, you do not have to undertake any action. You do not have to explain why you do not participate, although it would be instructive for the researchers to know your considerations.

You will decide with your doctor the best treatment policy for you. During participation, it is possible to withdraw from the study at any time. We still would like to ask you to fill out the questionnaires. The decision to do so will always be yours.

10. What happens when the study has ended?
The study ends after your last checkup. Your doctor will discuss the further course of your treatment.

When you decide to withdraw from the study, the study then ends immediately. Your doctor will discuss treatment options with you. Withdrawal from the study does not cause any risks for your health, nor will it affect the relationship between you and your doctor.

It is also possible that the researcher thinks it is not safe to continue the study and the *wait-and-see policy*. This could happen when the study shows bad results for this policy. The researchers must inform you about stopping the study and the reason why it stopped. If this happens, your doctor will discuss other treatment policies with you.

After completion of the study the results will be published. Your personal information will be used anonymously.

11. Do you have insurance when you participate?
You have insurance at all time by your own insurance and the liability insurance of the hospital. You do not need a special insurance for participation.

12. Will you be informed when relevant information will be announced?
The study is conducted according to a strict protocol. But it is possible that, during the study, your body reacts in a particular way or that new information will be revealed. If that happens, we will discuss these changes with you immediately. You can then decide if you would like to continue participation or not. If your health or wellbeing is in danger, the study will be stopped immediately.

13. What happens to your personal data?
The rules regarding the use of medical data are in the Act of Medical-Scientific Research with People. Please find any further explanations in the General Leaflet of the Government (only in Dutch, please find the URL at the last page of this letter).

14. Will your General Practitioner (GP) will be informed when you participate?
Your GP will not be informed regarding your participation in the study, because participation does not imply any limitations.

15. Does participation have any financial consequences?
There are no costs or rewards related to participation.

16. Which Medical-Ethical Committee has approved this study?
The Medical-Ethical Committee of the Erasmus MC has approved this study.

17. Would you like to know anything else?
You have 1 week time to make your decision. If you still have questions about the study after talking with your doctor, you can always contact the researcher. In case you would like to have independent advice, you can always contact the independent expert. Please find the contact data attached to this information letter.

18. Which other steps will be undertaken?
The researcher will call you 1 week after the appointment with your doctor. You will be asked if you participate in the study or not. If you participate, the researcher will explain which forms you need to complete. The researcher will ask you some questions, examples are listed below. Possibly, your physician asked (some of) these questions before. The reason why the researcher asks the questions again is because the researcher was no authorized to see your medical file yet.

Questions:
- Have you ever had surgery in the area of the tumor?
- Have you ever suffered any type of cancer?
- Which medication do you use?
- When did you noticed the tumor?
- Do you have complaints associated with the tumor?
- Women: Are you currently pregnant or have you ever been pregnant?

1. Checkup schedule

	Participation	Year 1				Year 2		Year 3-5		
Month		3	6	9	12	18	24	36	48	60
Medical questions and physical examination	X	x	x	x	x	x	x	x	x	X
MRI-scan	X		x		x		x	x		
Ultrasound	X	x		x		x			x	x
Questionnaire	X		x		x		x			x

2. Contact information

Researcher:
Drs. Milea J.M. Timbergen
Erasmus MC Cancer Institute
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Independent expert:
Dr. J.W.A. Burger
Surgical Oncologist
Erasmus MC Cancer Institute
Tel: 010-7041082

Expert responsible for this study in the NKI-AvL:
Dr. Frits van Coevorden
Oncologic surgeon
Tel: 020-5122995

General Leaflet about medical-scientific research from the Dutch government (only in Dutch):

http://www.rijksoverheid.nl/documenten-en-publicaties/brochures/2014/09/01/medisch-wetenschappelijk-onderzoek-algemene-informatie-voor-de-proefpersoon.html