Patient Information

Title of the Study

Standardised data collection for lung cancer patients treated with curative primary or post-operative radiotherapy, or chemo-radiation therapy (SDC lung).

Participants

The participants in this study are lung cancer patients.

Background

You have been diagnosed with lung cancer. Depending on the size, location and other characteristics of the tumour, your treatment will consist of surgery, chemotherapy, radiotherapy, or a combination of these treatments.

Purpose of the Study

The purpose of this study is to gain insight into the effectiveness of treatments in terms of survival and side-effects, and to identify factors that can predict outcomes. This is why we want to collect patients' medical data of before, during and after treatment.

Previous research has shown that genetic information can be a predictor of the treatment outcome. We therefore also want to collect genetic data as part of our study. The genetic information can be obtained by retrieving DNA from saliva.

Standard Treatment and Procedures

The medical treatment you will receive while taking part in this study will be identical to the standard treatment.

If you sign the consent form, your medical record will be stored in a research database. You will be asked to complete two short questionnaires at seven points throughout the study: before the start of the treatment, 4 weeks after the start of the treatment, 2 weeks after the treatment is completed, 3 and 6 months, and 1 and 2 years after the start of the treatment. The questionnaires contain questions about your general health, possible side-effects and quality of life. It takes around 10 minutes to complete. You will receive the first questionnaire from the radiotherapy department. After that the questionnaires will be sent to you by post. Your data will be analysed together with that of other patients.

Depending on the standard procedures of the radiotherapy department, they may arrange follow-up appointments. These appointments are not part of the study. If applicable, these appointments will be planned roughly 2 weeks after the radiation therapy and 3, 6, 12, and 24 months after the end of the radiation therapy. You will need to go to the hospital for these appointments.

Optional Participation in DNA study (saliva sample)

Saliva samples will be collected to investigate the predictive factors in the DNA. This is optional, so you are not required to give a sample if you don't want to. You can also take part in this study without giving a saliva sample, by giving us permission to use your medical records and by completing the questionnaires.

If you agree to give a saliva sample, this will be taken in the hospital. The saliva sample will be taken during a routine visit to MAASTRO Clinic as part of the preparation for your treatment. You don't need to arrange a special appointment to have the saliva sample taken. The sampling requires you to spit into a tube a number of times. You should not eat, drink, smoke or chew gum 30 minutes prior to the saliva sample. It takes between two and five minutes to fill the tube. Once the tube is full, it will be sealed and sent to the researchers. The saliva will be stored in a biobank.

Possible Benefits and Disadvantages

You will not benefit personally from taking part in the study. However, future patients may benefit from the results by receiving more accurate information regarding their prognosis and/or the expected side-effects of their treatment. After the analyses have been performed, neither you, your doctor, nor your GP will receive the results, as your data will have been coded and no personal results will be available.

There are no risks associated with the study. The only disadvantage of taking part is that it takes (a short) time to complete the questionnaires at specific points: before the start of the radiation treatment and 2, 3, 6, 12, 18 and 24 months after the treatment is completed. The questionnaire takes roughly 10 minutes to complete.

Voluntary Participation

Participation in the study is on a voluntary basis. If you decide not to take part or if you want to end your participation at any time, this will in no way affect the treatment or medical care you receive in this hospital. If you decide you no longer want to take part in this study, we will use the information you provided in the questionnaires and the saliva sample, unless you object. In that case your data and saliva sample will be destroyed.

Privacy Policy

The confidentiality of your data will be guaranteed. Your data will not be published and access to your data is restricted to the study coordinator or his/her assistant. Your data will be given a study number as a means of coding it. Your data and the saliva sample will be stored for at least 15 years. The processing and analysis of your coded saliva sample will be carried out by a laboratory assistant. If required, data may be passed on to regulatory bodies. Your privacy will be guaranteed in the publication of the results in scientific journals.

Reimbursements

You will not receive any reimbursement for taking part in the study.

What you need to know

You will be kept informed about any findings that may influence your decision to continue participation in the study. You will be given at least three days to consider your participation.

If you have any questions about your rights as a participant in a scientific study, your participation in this study and/or comments regarding this study, please contact your doctor or Dr. E. Troost, a radiotherapist-oncologist at MAASTRO Clinic, on +31 (0)88-4455666.