25.01.2024

PATIENT INFORMATION SHEET

Clinical study (MupetFaasi3/DECIDER)

Integration of multiple data levels to improve diagnosis, predict treatment response and suggest targets to overcome therapy resistance in high-grade serous ovarian cancer (MUPET Faasi3/DECIDER)

Based on medical examination, you are suspected of having a malignant ovarian tumour. We are asking you to participate in a clinical study that examines the biological properties of ovarian tumours and biological markers, which correspond to the behaviour of the tumours. The study uses tissue and cell samples collected during surgery as well as blood samples. The aim of this study is to find new information on how ovarian cancer metastasises and how its response to treatments can be evaluated. The study takes place at the Department of Obstetrics and Gynaecology of the Turku University Central Hospital (Tyks), and we estimate to enrol approximately 400 patients for it. The international DECIDER research consortium contributes to this study.

1. **Participation in the study**

Your participation is completely voluntary, and you have the right to discontinue participation at any stage without any explanation. You will not receive any payment for your participation. Please take your time to read through this information sheet carefully. If you have any questions, you may contact the doctor in charge of the study or other study personnel. If you decide to participate in the study, we will ask you to sign the attached consent form.

2. **Implementation of the study**

The recruitment of patients for the study, collection of samples and treatment of the patients take place at the Turku University Hospital (Tyks), Department of Obstetrics and Gynaecology. Analysis of the samples is performed in collaboration with research groups from University of Turku and University of Helsinki. The research groups are part of a European multicenter study. The wellbeing services county of Southwest Finland (VARHA) and University of Helsinki are data controllers of this study, and will be responsible for the legality of the processing of personal data collected for the study. The main funding for the study comes from the European Union, Syöpäsäätiö (Cancer Foundation Finland) and Academy of Finland.

Contemporary scientific research is carried out in collaboration with international research groups. We establish partnerships with specialists in EU countries and outside the EU to achieve the best possible results. You can follow our research and collaborators on our website (http://sites.utu.fi/ovariancancer).

The research has been approved by the VARHA Ethical Committee. The investigating doctor responsible for the study has no influence on the committee's decisions.

3. Background and aims of the study

Ovarian cancer is often diagnosed at an advanced stage, where chemotherapy is crucial in addition to surgery. This study examines the mechanisms of metastasis and behaviour of the tumours based on various DNA analyses and other biomarkers from blood and tissue samples. A specific aim of the study is to examine individual differences between the tumours and the possibility to find personalised treatments in the future.

4. Research methods

TISSUE SAMPLES

Your doctor is planning for you an operation, during which tumour tissue will be removed from the peritoneal cavity. Tissue samples required for diagnosis will be extracted from the tumour, and the remaining material will be used for scientific research. In case extra fluid (ascites) will be removed from the peritoneal cavity during this operation or later, a research sample will be extracted also from the fluid. Participation in this study will not add any additional procedures for you.

BLOOD SAMPLES

At the beginning of your participation in the study, a blood sample of 30 ml will be obtained. The sample is taken together with other blood samples related to surgical preparations. In case you are diagnosed with the most common ovarian cancer type, high-grade serous carcinoma, its treatment will require chemotherapy in addition to surgery. If the treatments are given at the Department of Obstetrics and Gynaecology of Turku University Hospital (Tyks), Tyks Salo Hospital, Satasairaala in Pori or Vaasa Central Hospital, blood samples for the study will also be taken in connection to the treatments and during follow-up. We will send you a letter when the diagnosis is confirmed.

During the first-line chemotherapy, two 30 ml blood samples will be collected for the study. These samples will be taken at the same time as other blood samples related to the treatments, one to two days before the chemotherapy or in the morning of the treatment day. A blood sample for this study will also be collected during the follow-up visits every six months up to three years. If your disease recurs, blood samples for research purposes will be collected three times during the chemotherapy.

THIS PART CONSERNS ONLY STUDY PATIENS WHO ARE EVALUATED WITH FDG PET/CT SCAN

A body scan (CT) is normally performed before surgery if advanced ovarian cancer is suspected. For this study, an additional FDG PET/CT scan will be performed in order to estimate the initial stage of tumour spread. FDG is a commonly used PET marker in diagnosis and follow-up of cancer. The expert statement from the scan will be included into your patient files and the information may be utilised in planning your treatment.

PET scans are performed at the Tyks PET Center and Satasairaala in Pori. On the day of the scan, a marker for imaging will be injected into your blood stream through an intravenous cannula and a PET/CT scan of your body will be performed. Except for cannulation, the imaging examination is painless. In total, the examination takes about 2 hours. The total radiation dose resulting from the

examination is on average about 16.6 mSv. The dose corresponds to the average effective radiation dose people in Finland are exposed to in a period of 2 years and 10 months.

If surgery is not possible in the initial stage due to tumour spread, the FDG PET/CT scan will be repeated after the chemotherapy treatments before more extensive surgery, in order to assess response to the treatments.

5. Benefits, harms and discomforts related to the study

Participation in the study will have no effect on the treatment that you receive and you will not receive immediate benefits for it.

For some patients, health-relevant findings may be discovered from their samples. If you wish, we will inform you of these findings. It is also possible that we could find some features in the tumours that can be targeted with personalized drug therapies. The information collected in the study may be used in case established treatments are not available (for example, ovarian cancer has recurred and progressed during standard medication and does not respond to conventional medication). In this case, we will inform you and the doctor responsible for your treatment.

The study will not cause any costs or extra visits to the clinic for you. The blood samples for the study will be collected in Turku, Salo, Pori or Vaasa by a nurse who is trained in sample taking.

6. Processing of the samples, confidentiality and review of the patient records

Your samples will be analysed with different methods to discover their characteristics in detail (for example, by drug sensitivity testing, genome-wide analysis of normal and tumour cells, by studying gene expression and the proteins made from those genes, as well as metabolites). While analysing the genome, we examine changes that occurred during the development of the disease (non-hereditary or somatic mutations) to understand how the disease originates and progresses. In addition to academic research laboratories, studies may also be conducted in companies in order to make use of the most high-standard technologies. The samples can also be analysed outside EU in countries, which are not under the EU data protection regulations. In these cases, data protection will be guaranteed by coding the samples and data, as well as with carefully drafted agreements on the handling of data and/or samples. The MupetFaasi3 Research Group is in charge of publishing the results of the study, and companies or collaborators cannot use your samples for other purposes.

Your identity and other identifying personal details are known only to the research personnel, who are under obligation to maintain secrecy. Data sharing within the DECIDER Research Consortium will follow Finnish and EU legislation and personal data is pseudonymized or anonymized. All the data and the samples collected regarding you will be processed in a coded form, so that your identity cannot be revealed from any of the research results, reports or publications.

Research materials that is used for scientific publications by the DECIDER Research Consortium, must be available for the global research community according to scientific principles. For this reason, secure genome data archival platforms, like the European Genome-Phenome Archive (EGA, https://ega-archive.org/) exist in Europe. The DECIDER project's genomic information is stored in

the EGA. This database is pseudonymised so individual patient data cannot be recognised or connected to a specific person. The DECIDER information stored in the EGA can only be used in research which complies with this patient consent agreement and in accordance with EU data protection regulations.

The legal basis for processing personal data here is public interest, scientific research (EU General Data Processing Regulation, GDPR and Data Protection Act § 4 ja §6). Only personal data necessary for the study will be saved in the research dataset. We will collect your laboratory results and information on operations, imaging studies, treatments and diagnoses from your medical case records. Findings from surgery and imaging may also be saved in digital image format. Your name or any other personal identifier (date of birth, contact information etc.) will not be given to research collaborators. In research results and other documents, you will be referred to only in code. The clinical research dataset will be kept at the Department of Obstetrics and Gynaecology of Tyks until the end of the study. If you decide to withdraw your consent, the data collected at the time of withdrawal will be used as part of the research data. This is necessary to ensure the validity of the research results and the safety of the subjects.

Auria Biobank promotes high standard medical research and the collection of patient materials for research. If you have given a separate biobank consent, any research samples and information collected in this study can be transferred to the AURIA Biobank and used in accordance with the Finnish Biobank Act.

Additional information

If you have any questions regarding the study, please contact the medical doctor in charge of the study or any other study personnel.

Research nurses Nina Halme /Tiina Vartiala

Department of Obstetrics and Gyneacology, Tyks
Phone: 02-313 9340 (Wednesday and Thursday)

Medical doctor in charge of the study, Docent Johanna Hynninen
Specialist in Obstetrics and gynaecology
Senior Consultant/ Gynaecologic oncology
Department of Obstetrics and Gyneacology, Tyks
johanna.hynninen@varha.fi

CONSENT

I have been asked to participate in the MupetFaasi3/DECIDER study.

I have read and understood the above patient information sheet, and received enough information on the data collecting, processing, and sharing in the study.

The content of this study has been explained to me also verbally and I have received satisfactory answers to all my questions regarding the study.

The study was explained to me by _____
. I have had enough time to consider participating in this study.

I understand that my participation is completely voluntary. I have the right to discontinue participation in the study or to withdraw my consent for participation at any stage of the study without providing an explanation. Such discontinuation of participation or withdrawal of consent will not result in any negative consequences or have any effect on my rights to receive further treatments. I am aware that information collected on me before discontinuation of participation or withdrawal of consent will be used as part of the research material and for drug safety evaluation.

I give my permission to be contacted in case there are research findings relevant to my health.

I agree that my samples, if not needed for this study, can be transferred to Auria Biobank, if I have given a separate Auria Biobank consent

With my signature, I confirm my participation in the study described in this document and give my consent to become a voluntary research subject. I give permission for the processing of my personal data in case of an audit by a foreign authority and in case of quality control review conducted by the funding authorities.

_____ _____

Signature Date

_____ _____

Name in block letters Date of birth or personal identity code

Consent received

_____Date and signature of person receiving the consent Name in block letters

The original consent form is kept in the records of the doctor in charge of the study. A copy of this form is given to the research subject