Enclosure D: Informed consent

TOTEM Study: Multicentric randomized controlled clinical trial between two follow up regimens with different tests intensity in endometrial cancer treated patients

INFORMED CONSENT

You have been surgically treated for an endometrial cancer and we would like to inform you that examinations done during diagnostic and therapeutic pathway show no more residual desease. Unfortunately the eventuality of a relapse exists: so it is very important to organize periodic visits and examinations for early detection of the onset of the relapse. All these visits and tests are called follow-up.
The medical staff of this center, along with other … Institutions, participates in a study that aims to determine the most suitable follow-up program for patients who were treated for endometrial cancer . The study compares two different control programs commonly used in clinical practice. These include the performance over time and with a certain frequency of clinic visits by doctors who have followed your terapeutic pathway and certain tests such as TC, ultrasound, PAP tests or blood examinations. The use of these diagnostic procedures is suggested from clinical experience so far, but there is no scientific evidence on the usefulness of their performance for the early detection of outbreak of any possible recurrence. Their impact on quality of life and damage caused in terms of stress and worry is unknown too.
The study, designed by a Scientific Committee composed of physicians and researchers and approved by the Ethics Committees of each participating hospital, was approved and funded by…
The expected benefits are the definition of an optimal scheme of follow-up.
Becoming part of this study is for you free of risks associated with the natural history of disease that was treated.
If you agree to participate, you will be advised to follow one of two control programs that is medical examinations and visits according to a calendar that will be delivered to you.
The choice of a program over another, as in all controlled clinical studies will be carried out randomly by the central data management.
As part of this study you will be asked to fill out a questionnaire at enrollment and then once a year; the purpose is to assess your state of wellness and your satisfaction about the program of visits and tests that have been proposed.
The adhesion to the study is of course free and you can withdraw from the program at any time, without impairing in any way the relationship with your physicians
The Organizing Committee of the Protocol is the owner of the data collected in this study and has taken all necessary measures to protect information collected about you and other patients who participate (archives dedicated locked, documents on a computer protected by password). Only doctors and researchers, ethics committee members and institutional bodies involved in this study have access to these data. Your name and any information that might identify you will never appear in any presentation or publication.
Please remember that you have the right to request information on the study and at the end of the study, if required, will be notified of the results obtained.

For further information and clarification on this study or any requirements during the study, if you decides to participate, please contact the Dr. ……., telephone …… that is at your disposal for any question or doubt.

The undersigned ……
has received and read, in addition to this form, separate information for the patient, had the opportunity to ask questions about the proposed study and agrees to participate in the study

Date ……

Patient's signature ……

Witness Signature……

Signature of responsible physician……