INFORMED CONSENT FOR OBSERVATIONAL STUDIES

APRIL 2023

Gemelli
Fondazione Policlinico Universitario Agostino Gemelli IRCCS
Università Cattolica del Sacro Cuore

INFORMATION SHEET FOR PARTICIPATION IN AN OBSERVATIONAL STUDY AND DECLARATION OF CONSENT FOR CAPABLE PEOPLE v 1.0 of 13.04.2023

U.O.C. General and Liver Transplant Surgery

Dear Sir/Madame,

At the Fondazione Policlinico Gemelli IRCSS of Rome (Italy) is planning a medical-scientific research entitled "Surgical or Medical Treatment of Breast Cancer Metastasis: a Multicentre Observational Study".

This research has a multicentric international character.

To carry out this research we need the cooperation and availability of people who, like you, meet the scientific requirements for the evaluation that will be carried out. However, before you make the decision to accept or refuse to participate, please read this document carefully, taking all the necessary time and ask us for clarification if you do not understand or need further information. In addition, if you wish, you can ask your family members or your doctor for an opinion before deciding.

WHAT THE STUDY PROPOSES

Primary aim of the study is to compare the efficacy of liver resection vs. medical therapy alone in Breast Cancer Liver Metastasis (BCLM) patients.

With this research, we intend to obtain data on the overall 5-year survival in patients with breast cancer undergoing liver resection or medical therapy alone.

WHAT YOUR PARTICIPATION IN THE STUDY ENTAILS

The study plans to do additional investigations on data recovered from the medical archives of each participating center for all patients enrolled retrospectively.

Prospective enrolled patient data will instead be collected in the relevant medical records and reported, together with all other patient data, in an electronic dataset protected by password and accessible only to the IP and coinvestigators, and any other person authorized by PI.

The study will overall last 68 months and foresees two distinct phases. The first phase (retrospective phase only) will cover all patients underwent medical or surgical treatment for which all data are available, with a follow-up of 5 years at March 31, 2023. The second phase (ambispective) will also include all patients recovered from archives between 1 April 2018 and 30 April 2023, as well as all patients prospectively enrolled until 31 December 2023, ending the 5-year follow-up by 31 December 2028.

720 patients will participate in this research, including 35 at this hospital.

RISKS ARISING FROM PARTICIPATION IN THE STUDY

Participation in the study does not involve any investigation or treatment other than that provided for in normal clinical practice and therefore there will be no additional risk in the study compared to clinical practice.

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WHAT BENEFITS YOU MAY RECEIVE FROM PARTICIPATING IN THE STUDY

Participation in this study is not directly beneficial to you, but your participation will allow us to acquire additional information about the disease that you are suffering from.

WHAT HAPPENS IF YOU DECIDE NOT TO PARTICIPATE IN THE STUDY

You are free not to participate in the study. In this case, however, you will receive all the standard therapies provided for your pathology, without any penalty, and the doctors will continue to follow you with due care.

INTERRUPTION OF THE STUDY

Your participation in this research programme is completely voluntary and you may withdraw from the study at any time by notifying the Investigator. In this case the data collected until the moment of withdrawal will be considered in the results in aggregate and anonymous form for the final analysis.

INFORMATION ON THE RESULTS OF THE STUDY

If you request it, at the end of the study you may be informed of the results of the study.

FURTHER INFORMATION

If you agree, it may be useful to inform your family doctor of your participation in this study.

For further information and communications during the study the following staff will be available:

- Dr. Francesco Giovinazzo, U.O.C. General and Liver Transplant Surgery, Department of Medical and Surgical sciences, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Largo Francesco Vito 1, 00168, Rome (Italy) - email: francesco.giovinazzo@policlinicogemelli.it - Tel: 0630154868
- Dr. Amelia Mattia, U.O.C. General and Liver Transplant Surgery, Department of Medical and Surgical sciences, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Largo Francesco Vito 1, 00168, Rome (Italy)

The protocol of the proposed study has been drawn up in accordance with the current reviews of the European Union Standards of Good Clinical Practice and the Helsinki Declaration of the World Medical Association on clinical trials involving human subjects and has been approved by the Ethics Committee of this structure. You can point out any fact that you consider appropriate to highlight, in relation to the experimentation that concerns you, to the Ethics Committee of this structure.

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DECLARATION OF CONSENT

DECLARE

☐ I have received a full explanation from Dr _____ about the request to participate in this research, as reported in the information section of which I have been given a copy before. A copy of this consent was delivered to me on _____

☐ which have been clearly explained to me and I have understood the nature, aims, procedures, expected benefits, possible risks and drawbacks;

☐ have had the opportunity to ask the investigator of the study any questions and have had satisfactory answers;

☐ that they have had to me sufficient time to reflect on the information received;

☐ they have had to me sufficient time to discuss this with other people;

☐ be aware that the research may be interrupted at any time;

☐ to have been informed that the results of the study will be send to the scientific community, protecting my identity in accordance with current privacy legislation;

☐ be aware that any choice expressed in this consent form may be revoked at any time and without any justification;

☐ I have received a copy of this consent form.

_____	_____
Data	Patient's signature
Data	Signature of the doctor who informed the patient

(If the patient is unable to read or sign, an independent witness from the experimenter and the sponsor must be present during the discussion of the informed consent. The witness must personally sign and date the informed declaration of consent after the form and any other written information has been read and explained to the subject and the subject has given verbal consent to participation in the study).

In this case:

I undersigned …….. testify that the doctor …… has exhaustively explained to Sig. ……
the characteristics of this experimental study, as reported in the information sheet, and that the patient had the opportunity to ask all the necessary questions and he freely agreed to join the study.

Date..... Signature of the independent witness ……..

Date..... Signature of the doctor who gave the information to the patient
……