INFORMATION LEAFLET AND INFORMED CONSENT

Title of the study	**The ADAPTA Study: adjuvant chemotherapy after resection with curative intent of ampullary cancer. A prospective study observational multicentric European .**
Acronym	**ADAPTA**
Promoter	Poliambulance Foundation
Principal Investigator	Prof. Mohammed Abu Hilal E: mohd.abuhilal@poliaccademia.it T: 0303518951
Operational unit	General surgery
Body	Poliambulance Foundation

Dear Madam(s),

In this hospital institute a medical-scientific research is planned entitled:

" The ADAPTA Study: adjuvant chemotherapy after resection with curative intent of ampullary cancer. A European multicenter prospective observational study."

This research, promoted by the Poliavventura Foundation, is multi-centre in nature, meaning that it also takes place in other structures besides ours.

To carry out this research we need the collaboration and availability of people who, like you, are affected by ampullary adenocarcinoma and meet the scientific requirements suitable for participation. Before you make the decision to accept or refuse to participate in the study, please read these pages carefully, taking all the time you need, and ask us for clarification if you do not understand or need further clarification. Furthermore, if you wish, before deciding, you can ask your family or a trusted doctor for advice.

All data provided will be processed in compliance with Legislative Decree 196/2003 as amended and with GDPR 679/2016 (European Data Protection Regulation), in accordance with the responsibilities established by the rules of good clinical practice (Legislative Decree 211/2003).

The data, processed using electronic tools, will only be disseminated in a strictly anonymous form, for example through scientific publications, statistics and scientific conferences. Your participation in the study implies that, in compliance with the legislation on trials, the Ethics Committee and the Italian and foreign health authorities will be able to know the data concerning you, also contained in your original clinical documentation, in ways that guarantee the confidentiality of your information. identity.

WHAT DOES THE STUDY PROPOSE?

This study includes patients with ampullary adenocarcinoma (AAC) characterizing them based on the pathological isotype defined following resection with curative intent. Different histotypes have shown different biological behaviors and therefore could benefit from chemotherapy treatments with adjuvant intent that are diversified and specific for the individual histotype . This study aims to evaluate the effect, defined in terms of disease-free survival (DFS), of a differentiated and specific adjuvant treatment for the different subtypes of Ampullary Adenocarcinoma (AAC): specifically, the FOLFIRINOX-based scheme in pancreatic-biliary and mixed subgroup, and CAPOX-based in the intestinal subgroup.

WHAT ARE THE BENEFITS YOU WILL RECEIVE BY PARTICIPATING IN THE STUDY

Recent clinical studies have highlighted how the biliary and mixed pancreatic subtype of ampullary adenocarcinoma present histopathological similarities with pancreatic adenocarcinoma and could benefit from a treatment based on FOLFIRINOX commonly used for the latter neoplasms. Otherwise, the intestinal subtype of ampullary adenocarcinoma presenting characteristics similar to intestinal cancer, commonly treated with CAPOX-based schemes, could benefit from the same therapeutic scheme. Given this evidence, a specific treatment could improve the disease-free survival of patients included in the study and treated with individual chemotherapy schemes.

WHAT ARE THE RISKS OF PARTICIPATING IN THE STUDY

The study is observational in nature and, therefore, will not add risk to the individual patient. The chosen therapeutic schemes are in fact already implemented in normal clinical practice.

WHAT DOES YOUR PARTICIPATION IN THE STUDY ENTAIL?

The nature of this study is observational, the patient will in fact follow his personal treatment without changes related to participation in the study. The patients participating in the study will be followed throughout their journey and will give their consent to the collection of their clinical, pre -peri- and post-operative data, as well as anatomopathological data. During the follow up, i.e. at 3, 6, 9, 12, 18

and 24 months, the patient will also be asked to complete a short questionnaire to evaluate his quality of life. The compilation will take place electronically or during the normal outpatient visit.

WHAT HAPPENS IF YOU DECIDE NOT TO PARTICIPATE IN THE STUDY

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

STUDY INTERRUPTION

Your participation in this research program is completely voluntary and you may withdraw from the study at any time. In case of revocation of consent, any biological material provided will be destroyed, unless it can no longer be identifiable.

INFORMATION ABOUT THE RESULTS OF THE STUDY

If you request it, the final results of the study may be communicated to you at the end of the study.

FURTHER INFORMATION

For further information and communications during the study, the following staff will be available: Prof. Abu Hilal, Medical Director in charge of the General Surgery Department of the Poliambulance Foundation Hospital Institute Tel. 0303518951.

The study protocol proposed to you was drawn up in compliance with the European Union Standards of Good Clinical Practice and the current revision of the Declaration of Helsinki and was approved by the Brescia Ethics Committee.

INFORMED CONSENT

For participation in the Study

The ADAPTA Study: adjuvant chemotherapy after resection with curative intent of ampullary cancer. A European multicenter prospective observational study

1 - Date of acquisition of consent:

2 - Patient details

Surname ……

First name ……

Date of birth……

Patient sticker

3 - Questions asked by the patient, clarifications, notes:

4 – Upon completion of the information and before signing this consent, the brochure/explanatory leaflet is delivered.

Title
INFORMATION LEAFLET AND INFORMED CONSENT

The ADAPTA Study: adjuvant chemotherapy after resection with curative intent of ampullary cancer. A European multicenter prospective observational study

5 - Declarations by the interested party

With this declaration, to be considered a full, free and unconditional manifestation of my will, ***I declare*** *, in full possession of my mental faculties, that I have received from the doctor who exposed the contents of this consent to me, exhaustive explanations regarding the request for participation in the experimental study in question, as reported in the information sheet attached here, a copy of which was given to me before now.*

declare *that I have been able to discuss this information, to ask all the questions I deemed necessary and to have received satisfactory answers, as well as to have had the opportunity to inform myself about the details of the study with a person I trust and I undertake to communicate to my trusted doctor and to all the other doctors with whom I am being treated for my enrollment in the trial and I authorize the experimenter to contact my other treating doctors.*

I therefore freely accept to participate in the trial, having fully understood the meaning of the request and having understood the risks and benefits involved.

I was also informed of my right to have free access to the documentation relating to the trial (insurance, clinical-scientific, pharmaco-therapeutic) and to the evaluation expressed by the Ethics Committee of Brescia. And *I am aware* that all the data provided will be processed in compliance with Legislative Decree 196/2003 as amended and with GDPR 679/2016 (European Data Protection Regulation), in accordance with the responsibilities established by the rules of good clinical practice (Legislative Decree 211/2003).

I believe that the exposition of what has been described above occurred ***in a clear and understandable way and I consider the time given to me to evaluate the contents and to ask any questions as appropriate*** *. I am satisfied with the answers I received and* ***I had the time necessary*** *to be able to make my decisions calmly.*

I declare that I have informed *the doctors in detail about the previous surgical interventions I have undergone, the pathologies I am currently suffering from and the ongoing medical therapy.*

I therefore consent and expressly request to be subjected to the experimentation covered by this consent

I also request that my clinical conditions and the results of the intervention/procedure be informed:

☐ *first degree relatives* ☐ *the following person* ☐ ***DO NOT*** *inform anyone*

Name Surname *Degree of kinship*

SIGNATURE OF THE INTERESTED PARTY	***DOCTOR'S SIGNATURE***	***INTERPRETER'S SIGNATURES***

Signature of the guardian/Support Administrator *Attach a copy of the decree appointing the guardianship judge (pursuant to Law 9 January 2004, n°6 et seq .)*	***Parents' signature*** *(in case of a minor patient)*

INFORMATION AND CONSENT FOR DATA PROCESSING PERSONAL: DECISION OF THE PRIVACY GUARANTOR n. 52 OF 24 JULY 2008

Information and expression of consent to the processing of personal data

Data controllers and related purposes

The Poliambulance Foundation Experimentation Center took part in the study described to you. As part of this study, in accordance with the responsibilities established by the rules of good clinical practice (DL 211/2003), you will process your personal data, in particular health data and, only to the extent that they are indispensable in relation to the objective of the study, other data relating to your origin, your lifestyle and your health history exclusively for the purpose of carrying out the study. To this end, the indicated data will be collected by the Testing Center. The processing of personal data relating to health data is essential for carrying out the study: refusal to provide them will not allow you to participate.

Nature of the data

The doctor who will follow you in the study will identify you with a code: the data concerning you collected during the study, with the exception of your name, will be recorded, processed and stored together with this code, your date of birth and sex. Only your doctor and authorized individuals will be able to link this code to your name.

Treatment methods

All data provided will be processed in compliance with Legislative Decree 196/2003 as amended and GDPR 679/2016 European Data Protection Regulation), in accordance with the responsibilities established by the rules of good clinical practice (Legislative Decree 211/2003).

The data, processed using electronic tools, will only be disseminated in a strictly anonymous form, for example through scientific publications, statistics and scientific conferences. Your participation in the study implies that the Ethics Committee of Brescia and the Italian health authorities will be able to know the data concerning you, also contained in your original clinical documentation, in ways that guarantee the confidentiality of your identity.

Exercise of rights

You may exercise the rights referred to in the articles. 15-22 GDPR 679/2016 (e.g. access your personal data, integrate them, update them, rectify them, object to their processing for legitimate reasons, etc.) by contacting the Poliambulance Foundation testing center directly – Privacy Office – privacy@poliavventura.it).

You may interrupt your participation in the study at any time and without providing any justification: in this case, the biological samples related to you will be destroyed. Furthermore, no further data concerning you will be collected, without prejudice to the use of any data already collected to determine, without altering, the results of the research.

Consent

By signing this form I consent to the processing of my personal data for research purposes within the limits and in the manner indicated in the information provided to me with this document.

Name and surname of the interested party (in block letters) _____

Date _____ Signature of the interested party _____

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