INFORMED CONSENT FORM

CLINICAL TRIAL PROTOCOL

RANDOMIZED, CONTROLLED, OPEN AND UNICENTRIC PHASE II CLINICAL TRIAL, WITH TWO PARALLEL GROUPS, TO EVALUATE THE ANTIDEPRESSANT EFFICACY OF PSYCHOTHERAPY AND CITALOPRAM IN WOMEN DIAGNOSED WITH BREAST CANCER AND MAJOR DEPRESSION. CAMAD PROJECT

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Protocol Number: HUB-PSI-CAMAD
EudraCT Number: 2019-004548-31

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Principal Investigator and Sponsor: Dr. Cinto Segalàs Cosi
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We are writing to inform you about a research study in which you are invited to participate. The study has been approved by an Ethics Committee for Investigation with medical products (CEIm) and the Spanish Agency for Medical Products and Medical Devices (AEMPS), in accordance with the current legislation, Royal Decree 1090/2015, of 4 December, and by the European Regulation 536/2014, of 16 April, regulating clinical trials and medicinal products.

Our intention is for you to receive correct and sufficient information so that you can decide whether or not to participate in this study. Please read this information sheet carefully and ask us to clarify any questions you may have.

You should know that your participation in this study is voluntary and that you can decide NOT to participate. If you decide to participate, you can change your decision and withdraw your consent at any time, without this affecting your relationship with your doctor or causing any penalty to your treatment.

Introduction:

A significant number of patients with Breast Cancer (BC) (25%) develop Major Depression (MD), with an especially increased risk the first year after the BC diagnosis. Comorbid depression is associated in BC with higher mortality in younger patients and in early states of the disease, as well as with a decreased acceptance and compliance of adjuvant therapy that consequently worsens the course and prognosis of BC.

Taking into account that the highest risk period to develop MD in patients with BC is the first year after malignancy diagnosis, the screening and early diagnosis of MD in BC patients is crucial to improve the course and prognosis of the BC. Psychopharmacological and psychological treatments are useful strategies in the treatment of depression. Nonetheless, controlled-randomized clinical trials that compare the antidepressant efficacy of both methods have not been conducted. Moreover, no predictors of response to a certain treatment (psychological or psychopharmacological) have been analyzed.

Study objective:

The purpose of the present study is to evaluate the antidepressant efficacy of two treatment strategies: citalopram vs psychotherapy, and to test whether markers could emerge as predictors of response, which would allow the design of tailored and more effective treatment strategies for patients with BC and MD.

Benefits:

Your participation in the study will contribute data to advance the knowledge of efficacy and safety of both antidepressant treatments, as well as predictors of response.

Study procedures:

A total of 40 patients are expected to be involved in the study, 20 patients will receive pharmacological antidepressant treatment (citalopram) and the other 20 will receive psychotherapy as antidepressant treatment. Both kinds of treatment will be assigned randomly.

If you decided to participate in the study, a first in-person visit will be conducted to verify the inclusion criteria. Once included in the study a specific antidepressant treatment will be assigned: psychotherapy or citalopram.

Socio-demographic data and current medical treatment will be collected. Also, a neuropsychological test will be performed.

Regardless of assigned treatment, you will have 12 weekly, online follow-up visits in order to evaluate antidepressant efficacy with clinical assessment scales. You will also be required to answer clinical assessment scales via email.

Throughout the follow-up, you should inform about any adverse event or changes in the prescribed treatment. We suggest that you do not modify the treatment you are taking or take any other medications (medicinal plants included), without asking your doctor. All the changes in the oncologic treatment and their side effects will be collected.

In accordance with the technical data sheet, citalopram is contraindicated:

-Monoamine oxidase inhibitors (MAOI) or the reversible MAOI (RIMA).
-Linezolid.
-Class IA and III antyarrhytmics.
-Antipsychotics (haloperidol, pimozide, fenotiazina).
-Tricyclic antidepressants.
-Anti-malarial drugs (Halofantrine).
-Sparfloxacin, moxifloxacin, eritromicina IV and pentamidine.
-Antihistaminics (astemizole, mizolastine).

Risks and side effects:

Side effects of citalopram are minimal and include nausea and transient abdominal pain at the beginning of the treatment or as the doses increase. Citalopram is safe for patients with kidney and/or liver disease and interactions with any other medications has not been reported, except for patients suffering from arrhythmias.

Citalopram has been approved by the competent health authorities; there is information accessible to everyone on the side effects of the drug citalopram. Please talk to your doctor to obtain the list of the side effects of citalopram, in any case the drug leaflet will be provided. Any new information related to citalopram that could affect your involvement in the study will be reported to you by your doctor as soon as possible, and if necessary a new informed consent form will be signed.

No side effects have been reported with psychotherapy as antidepressant treatment.

If you decided to participate in the study a careful monitoring of any adverse event related to citalopram will be done to ensure your safety.

If you become pregnant during your participation in the study, you should inform your doctor immediately to receive appropriate medical care. Data about the effect of citalopram in pregnancy and breastfeeding are unknown.

This study complies with current legislation (Royal Decree 1090/2015) and is considered of low level intervention. For this reason, any health problem arising from your participation in the study, except worsening of the underlaying disease (BC), is covered by the insurance hospital policy. If you would like more information about this section, consult the principal investigator of the study.

We inform you that it is possible that your participation in this clinical trial may modify the general and particular conditions (coverage) of your insurance policies (life, health, accident, etc.). Therefore, we recommend that you contact your insurer to determine whether your participation in this study will affect your existing insurance policy.

The sponsor is responsible for managing study funding. You will not have to pay for the study drugs or the specific tests of the study. Your participation in the study will have no additional cost to the one you would have had in normal clinical practice.

Other relevant information:

You should also understand that you may be withdrawn from the study if the sponsor or study investigators deem it appropriate for safety reasons, for any adverse event due to the study drug, or because they think that you are not complying with the established procedures (adherence to drug therapy and attendance to psychotherapy sessions), medical issues (diagnostic of cerebral metastatic disease, pregnancy/breastfeeding), and psychiatric (psychiatric hospitalizations). In any case, you will receive an adequate explanation of the reason you have been withdrawn from the study.

Personal data protection:

The sponsor and the center undertakes to adhere to the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), as well as the rest of the applicable legislation (Organic Law 3/2018, of December 5, Protection of Personal Data and Guarantee of Digital Rights). Data collected for the study will be identified by a code, so that it does not include information that can identify you, and only your study doctor/staff will be able to link such data to you and your clinical records. Your identity will therefore not be disclosed to any person, except in the event of a medical emergency or as required by law.

Access to your identified personal information will be restricted to the study doctor/staff, regulatory authorities (Spanish Agency of Medicinal Products and Medical Devices, foreign health authorities), Ethics Committee for Investigation with medicinal products (CEIm) and staff authorized by the sponsor (study monitors, auditors), when required to verify the study data and procedures, but maintaining confidentiality at all times according to current legislation.

The data will be collected in a research file of the institution and will be processed in the context of your participation in this study. The data of this study could be used in future research. The sponsor will take appropriate measures to ensure the protection of your privacy and will not allow your data to be cross-referenced with other databases which would allow your identification.

According to data protection legislation, you may exercise your right of access, modification, opposition and cancellation of data, for which you should contact your study doctor. In addition, you can also limit the processing of data that are incorrect, request a copy or transfer to a third party (portability) the data that you have provided for the study. To exercise your rights, you may contact the principal investigator or the Institution Data Protection Officer, email: dataprotection@idibell.cat.

If you decide to withdraw your consent to participate in this study, no new data will be added to the database, but the data that have already been collected will be used. Also, in this study your electronic health record will be consulted to track safety follow-up data one month after the medical discharge. You may ask the Data Protection Agency if you are not satisfied.

The Investigator and the Sponsor are obligated to keep the collected data for up 25 years after finishing the study. Your personal data will keep in the Medical Center for health reasons, and will be accessible by the Sponsor for research purpose if you give your consent and if the law and ethic requirements allow it.

The coded data may be transmitted to third parties and other countries but in no case will they contain information that can identify you directly, such as name and surname, initials, address, social security number, etc. Should this transfer occur, it will be for the same purposes as the described study or for use in scientific publications, but always maintaining the confidentiality of the data in accordance with current legislation. If you need more information please contact with Promoter Data Protection Officer: Dr. Cinto Segalàs (csegalas@bellvitgehospital.cat).

If during your participation you have any question or need to obtain more information, please contact:
Dr. Cinto Segalàs Cosi
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What treatment will I receive when the clinical trial is ended?:

When your participation ends, you will receive the best available treatment that your doctor considers most appropriate for your disease, but you may not be able to continue receiving the study medication. Therefore, neither the investigator nor the sponsor take on any commitment to maintain such treatment outside of this study.

Participant Consent Form / Informed Consent

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I, (first name of the participant)_____

☐ I have read the information sheet given to me about the study.
☐ I have been able to ask questions about the study.
☐ I have received enough information about the study.
☐ I have talked with <<*name of investigator*>>
☐ I understand that my participation is voluntary.
☐ I understand that I can withdraw from the study:

- Whenever I wish.
- Without having to give explanations.
- Without this decision affecting my medical care.

I will receive a signed and dated copy of this informed consent document.
I freely consent to participate in the study

Signature of participant

Date: ____/____/____

Signature of investigator

Date: ____/____/____

(Name, signature and date in handwriting by patient)