HOSPITAL DAS CLÍNICAS DA FACULDADE DE MEDICINA DA UNIVERSIDADE DE SÃO PAULO-HCFMUSP
INSTITUTO DO CÂNCER DO ESTADO DE SÃO PAULO

Autologous heterotopic Fresh Ovarian Graft in young woman with locally advanced Cervical Cancer, eligible for pelvic radiotherapy treatment

Informed Consent Form

São Paulo, SP – Brazil

June 1st, 2022.

Research Data

Title: Autologous Heterotopic Fresh Ovarian Graft in Young Woman with Locally Advanced Cervical Cancer Eligible for Pelvic Radiotherapy Treatment

Main researcher – Jesus Paula Carvalho, PhD.
Departament – Gynecological Oncological Service – ICESP.

Executant researcher – Marilia Albanezi Bertolazzi, MD.
Executant researcher – Maria Luiza Nogueira Dias Genta, PhD.

Department/Institute - Service of Gynecological Oncological Surgery at ICESP.

Invitation to participate

We invite you to participate in scientific research. Research is a set of procedures that seeks to create or increase knowledge about a subject.
You were invited to participate in this research because you have an indication of undergoing radiotherapy treatment.
This treatment, despite being the most suitable for your type of tumor, has ovarian failure as a side effect. This means your ovaries will stop producing hormones and you will the diagnosis of menopause many years earlier than the average woman. Thus, you may feel signs of a lack of hormones. Although there is no contraindication to hormonal therapy in patients with cervical cancer, there are no medications available for this purpose at ICESP pharmacy. Most of patients cannot access medication – either due to unavailability or lack of knowledge on the part of professionals working in the basic health network regarding the indications and contraindications of this type of treatment or even for fear of using synthetic hormones.
This study aims to minimize problems arising from a lack of hormones by trying to get your ovary working elsewhere in your body before radiation therapy starts.

1. **Research objective**

This research aims to assess whether it is possible to maintain the production of female sex hormones by ovarian tissue engrafted in the fatty tissue. This hormone production is important for you to avoid early menopause symptoms (hot flashes, night sweats, frequent tiredness, mood swings such as irritability, anxiety or sadness), bone problems (osteoporosis), heart problems (cardiovascular diseases), atrophy in the urinary and vaginal system and increased risk of neurological diseases (such as Alzheimer's disease).

2. **Procedures that will be performed and methods**

If you accept to participate in this research, a prize draw will define which group you will be included.
(1) Intervention group: The ovaries will be removed through laparoscopic surgery (no cuts, only small stitches in the umbilical region and lower abdomen for insertion of forceps). Fragments of your own ovary containing cells capable of producing natural hormones will be implanted in the fat of your inner thigh. This procedure will be performed under general anesthesia, in the ICESP surgical center, under hospital admission. You will come to the hospital, have the surgery, and be discharged the next day, if you are doing well. The goal is to get your ovaries out of the radiation field. A small fragment of your ovaries will be kept at ICESP. The other procedures of your treatment will be according to the routine of the Institution. According to the current routine of the service, hormones will not be prescribed.
(2) Control group: You will perform the standard treatment currently available in ICESP and complementary exams to evaluate and monitor the effects of radiotherapy on your body. According to the current routine of the service, hormones will not be prescribed.
In both groups, you will perform, in addition to conventional follow-up tests, additional blood and imaging tests, as well as questionnaires to assess your quality of life.
Your blood samples will be stored at ICESP, in case additional tests are needed. You will need to consent to such storage in writing, with a consent form like this one.

3. **Explanation of possible discomforts and risks arising from participation in the research.**

The surgical procedure offers a minimal risk of complications such as: postoperative bleeding or pain, infection or related operative wound complications, risk of unsightly scar formation, need to remain hospitalized after performing laparoscopy.
There is no risk of rejection of the transplanted ovaries because it is an autologous transplant (your ovaries will be implanted in yourself).
To avoid possible risks or discomforts, all the procedures of this research will be carried out by experienced, trained and qualified professionals for each specific activity.
You should contact ICESP emergency service whenever you need. All participants will be guaranteed assistance for any problem arising from any intervention in this study.

4. **Expected benefits for the participant**

We still don't know the real benefit, but we believe that these relocated ovaries in your body could reduce the symptoms of early menopause, osteoporosis, cardiovascular disease, genital and urinary system atrophy. The intervention procedure - implantation of ovarian tissue - can overcome the consequences of the loss of hormonal function caused by radiotherapy and improve your life quality. The results from this study might change the standard treatment and change the life of other women with cervical cancer.

5. **Follow-up and assistance**

You will be monitored by the team of researchers for a minimum period of two years. Your follow-up in ICESP will have a minimum period of 5 years.

You should contact the ICESP emergency service whenever you have any issues or complications. All participants will be guaranteed assistance for any problem arising from any intervention in this study.

6. **Guarantees of full freedom to the participant to refuse to participate or withdraw their consent at any stage of the research without any penalty.**

The choice to participate in this study is entirely yours. If you refuse to participate in this study, you will receive usual treatment. As a participant, you have the right to withdraw from the study at any time, without prejudice of your treatment.
Your data will be analyzed with other research participants, and the identification of any patient will not be disclosed under any circumstances. We request your authorization to use data obtained in this research in a scientific publication. The results of a research are disseminated and shared with the scientific community.

7. **Guarantees of reimbursement for expenses arising from the research and guarantee of indemnification for any damages resulting from the research**

There are no personal expenses for the participant at any stage of the study, including examinations and consultations. The additional assessments you will perform will be included in your follow-up appointments and exams. Thus, the only additional trip to ICESP will be for the laparoscopy procedure. If you need financial assistance for this displacement, you can request reimbursement. There is also no financial compensation, your participation in this research is voluntary.

You will have the right to claim compensation for any damages resulting from the research.
At any stage of the study, you will have access to the professionals responsible for the research for clarification of doubts. The principal investigator is Prof. Dr. Jesus Paula Carvalho, that can be found at Av. Dr. Arnaldo, 251 – Cerqueira César – São Paulo - Telephone(s) 3893-2670 or (11)96792-0175, mail jesus.carvalho@hc.fm.usp.br or jesuspaulacarvalho@gmail.com.
If you have any concerns or If you have any questions about research ethics, please contact the Research Ethics Committee (CEP) – Rua Ovídio Pires de Campos, 225 – 5º andar – tel: (11) 2661-7585, (11) 2661-1548, (11)) 2661-1549, from 7 am to 4 pm from Monday to Friday or by mail: cappesq.adm@hc.fm.usp.br.

You have been sufficiently informed about the study “Heterotopic Autologous Implantation of Fresh Ovarian Graft in Young Women with Locally Advanced Cervical Cancer Eligible for Pelvic Radiotherapy Treatment”.

Have you discussed the above information with one of the researchers - Responsible Researcher Prof. Dr. Jesus Paula Carvalho, performing researchers: Maria Luiza Nogueira Dias Genta and Marília Albanezi Bertolazzi.
The purposes of the study, the procedures to be carried out, its discomforts and risks, the guarantees of confidentiality and permanent clarifications were here clarified.
It was also clear that your participation is voluntary, and you will be able to access to hospital treatment when necessary.
You voluntarily agree to participate in this study and may withdraw your consent at any time, before or during this study, without penalty, prejudice or loss of any benefit that you may have acquired from or in your service on this Institution.

You will sign two equal copies of this document, one of which we will remain with, and the other way will be delivered to you.

_____ Date _____/_____/_____

Participant signature

_____ Date _____/_____/_____

Witness signature

(Only for the project manager)
I declare that I have properly and voluntarily obtained the Free and Informed Consent from this patient or legal representative to participate in this study.

_____ Date _____/_____/_____

Project manager signature