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Descriptive abstracts

Autologous Heterotopic Fresh Ovarian Graft in Woman with LACC Eligible for Pelvic Radiotherapy Treatment

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Abstract

Background: Pelvic chemoradiotherapy (CRT) is an effective treatment for Locally Advanced Cervical Cancer (LACC). However, CRT induces premature ovarian failure ceasing the production of ovarian hormones. This may lead to severe consequences to the patient's life quality, sexuality and overall healthy. An acceptable treatment to minimize the adverse effects caused by the lack of ovarian hormones is hormonal replacement but less than 40% of the patients younger than 50 years have access to this treatment. A second alternative treatment is ovarian transposing which is a surgical technique with variable success rate depending on how far the ovaries are from the radiotherapy field. A third, more promising, alternative is involves using autologous ovarian tissue as a graft in tissues far from the radiotherapy field. This treatment has the potential of maintaining the natural ovarian hormones production at a lower-cost and requiring a simpler procedure. Objective: The primary objective of this randomized phase 1-2 clinical trial is to validate the feasibility of ovarian tissue engraft into fatty tissue and its endocrine functionality. Methodology: Before the beginning of pelvic radiotherapy, one of the ovaries will be removed by laparoscopy. Ovary slices of 1-2 mm will be prepared in sterile environment and engrafted in the fatty tissue of inner tight. One representative fragment will undergo histologic evaluation. These procedures will be done in the same surgical time.

Key words:Cervical cancer, premature ovarian failure, ovarian graft, hormonal replacement, ovarian function, pelvic radiotherapy.

Procedure: Ovarian graft

Before the beginning of pelvic radiotherapy, one of the ovaries will be removed by laparoscopy. Ovary slices of 1-2 mm will be prepared in sterile environment and engrafted in the fatty tissue of inner tight. One representative fragment will undergo histologic evaluation. These procedures will be done in the same surgical time.

Sample

20 Patients, 10 in each arm (control and intervention group).

Follow-up

Periodic evaluation of the following parameters at baseline and post radiotherapy (2, 6, 12 and 24 months):

-Serum levels of follicle stimulating hormone (FSH) in mUI/ml and estradiol in pg/ml. Endocrine functionality is defined as FSH levels under 25 mUI/ml and estradiol upper 47 pg/mL.

-Glucose, glycated hemoglobin, cholesterol, triglycerides.

-Score life quality in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ C30),

Periodic evaluation of the following parameters at baseline and post radiotherapy (12 and 24 months):

-Bone mineral density (BMD) in femoral neck and lumbar spine by bone densitometry, bioimpedance monitoring, quantification of body mass index.

-Score life quality in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30

(EORTC QLQ C30) and Score life quality in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 Cervical Cancer Module (EORTC QLQ C30 CX24)

Results

This trial is in recruiting phase.

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