ENDOMETRIAL CANCER RESEARCH

*"Retrospective study on the assessment of the use of **U**terine **M**obilisers in **E**arly-Stage **E**ndometrial **C**ancer: **MUCEI study**"*

Study design

The insertion of a uterine manipulator creates a positive pressure on the endometrial cavity which, hypothetically, would facilitate the passage of tumour cells through the tubes into the peritoneal cavity. In other words, it would contribute to the spread of the disease to other regions thanks to the access of these cells to other intra-abdominal organs. It is also associated with a higher rate of uterine rupture during use, breaking uterine integrity, exposing tumour cells to the pelvic cavity and/or vagina. Despite all of this, it has not been possible to demonstrate a worse oncological outcome derived from the use or non-use of a uterine manipulator, which is a highly controversial issue.

With the recent publication of data from the *LACC* (Locally advanced cancer of the cervix) phase III study questioning not only the use of the manipulator in hysterectomies for cervical cancer, but also the type of approach (laparotomy *vs* laparoscopy), the use of these devices has also been called into question in other types of gynaecological cancers such as, in this case, endometrial cancer.

This is a retrospective multicentre study in which a review of all patients who underwent surgery for apparent early-stage endometrial neoplasia will be conducted, classified according to whether or not a uterine mobiliser was used. We will analyse the pre-surgical characteristics of the patient, the surgical procedure, histological data, adjuvant treatment, relapses (PFS) and treatment, the relapse rate and overall survival (OS). We will assess the recurrence pattern and whether there are differences between the approach and the uterine mobiliser.

Objectives of the study

PRIMARY Objective

To retrospectively assess the rate of: local, locoregional and distant relapses in patients who have received primary surgical treatment for apparent early stage endometrial cancer, relating this to whether or not a uterine manipulator was used and the route of approach.

SECONDARY Objectives

1.- To assess the influence of possible risk factors contraindicating the use of a uterine mobiliser.

2.- To conduct an epidemiological study of the pre-surgical characteristics of women with endometrial cancer.

3.- To gather and analyse the characteristics of the surgical procedure, the histological data and the adjuvant treatment received.

4.- To calculate the relapse rate, disease-free survival and overall survival of these patients. As well as treatment of relapse.

Inclusion and exclusion criteria

Inclusion criteria

1.- Women with endometrial cancer diagnosed at an apparent early stage in the preoperative study, including stages I, II and III after histological study.

2.- Previous pre-surgical biopsy with a diagnosis of endometrial cancer or high suspicion of oncological pathology at myometrial and/or endometrial level.

3.- Operation has been performed and full details of the surgery, pathology and follow-up are on record.

4.- Follow-up longer than 2 years from the date of surgery.

Exclusion criteria

1.- Women with advanced stage endometrial cancer (evidence of extrauterine pathology and extensive cervical involvement).

2.- Use via vaginal route

3.- No follow-up data or loss of the patient

4.- Follow-up under 2 years

Eligibility for participation

1. Experience in gynaecological oncology surgery for endometrial cancer is required, at least 15 surgeries for endometrial neoplasia surgery per year recruited.
2. A favourable report with the acceptance of the study by the Hospital's Ethics Committee is mandatory.
3. Access to patient history and data collected in the attached database is mandatory.
4. The person in charge of the centre must have a valid certificate attesting to the successful completion of the Good Clinical Practice in Research Course.

   https://www.aemps.gob.es/industria/inspeccionBPC/docs/guia-BPC_octubre-2008.pdf

Data Management

Researchers agree to treat data in the strictest confidentiality in accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on Data Protection (GDPR) and Organic Law 3/2018 of 5 December on the Protection of Personal Data and the Guarantee of Digital Rights.

The person in charge of the centre shall be responsible for accurate recording and verification of patient data. Patients included in the study will be identified only by a numerical code. The dissociation procedure will be carried out by the researchers participating in the study, who will create a list in which the personal data of the patients will be related to the assigned code that will identify the patient during the study. The data generated during the study will be protected from unauthorised use by persons not involved in the research and will therefore be considered strictly confidential. A file will be created containing all the study documentation, which will be safeguarded by the principal investigator.

Financial report

The study has no sponsorship from industry or any other source; its economic report is zero.

Timeline

Compilation of databases: April 2019 to August 2019 = **5 months**

Data analysis and preparation of manuscript: September 2019 to December 2019= **3 months**