

Unique Protocol ID № 210

Endometrial Tissues and Mononuclear Cells Receptivity in Pathogenesis of Endometrial Proliferative Processes

Study protocol

Purpose of the study

To evaluate the role of the expression of estradiol and progesterone receptor genes in endometrial tissue and peripheral blood mononuclear cells in the occurrence of endometrial proliferative processes in postmenopausal patients with a pathogenetic justification for the choice of treatment method

Research objectives

- To determine the expression of estradiol (ER α , ER β , mER) and progesterone receptor genes (PRA, PRB, mPR, PGRmC1) in endometrial tissue with hyperplasia without atypia, atypical hyperplasia, adenocarcinoma and endometrial polyps as a control group in postmenopausal patients
- To determine the expression of estradiol and progesterone receptor genes in peripheral blood mononuclear cells in postmenopausal patients with polyps, atypical hyperplasia, endometrial adenocarcinoma and in healthy women of the same age (control group)
- To compare the expression of estradiol and progesterone receptor genes in endometrial tissue and peripheral blood mononuclear cells in patients with endometrial proliferative processes, depending on the nature of the pathological process
- To research the effect of progesterone and mifepristone on the receptor profile of peripheral blood mononuclear cells experimentally (in ex vivo conditions)
- To develop new pathogenetic approaches to treatment endometrial proliferative processes in postmenopausal patients

Research period: 2012-2022

Duration of treatment for an individual patient: from 3 to 12 days.

Number of patients: 90

Inclusion criteria:

The study included 90 postmenopausal patients with various endometrial proliferative processes (endometrial polyps, endometrial hyperplasia without atypia, atypical endometrial hyperplasia, endometrial cancer).

Exclusion criteria were: taking hormonal drugs for 6 months before inclusion in the study (COC, gestagens, GnRH, MHT, tamoxifen, etc.), uterine fibroids, more than 6–

7 weeks of pregnancy, uterine appendages pathology according to pelvic ultrasound examination, severe extragenital pathology, inflammatory diseases of any localization at the time of specimen collection, and the presence of autoimmune diseases

Design Research:

Researchers plan to examine 90 postmenopausal patients with endometrial proliferative processes who are hospitalized at Hospital No. 31, Moscow, from 2012 to 2022.

Researchers will evaluate:

- Assess medical data: height, weight, body mass index, activity indicator, gynecological history, reproductive history, family history, COC and MHT use, concomitant pathology.
- Carry out standard treatment methods: hysteroscopy with dilation and curettage and possible simultaneous intrauterine surgery (polypectomy, electrosurgical resection of the endometrium in the first stages and hormonal therapy according to indications in the last stages.
- To investigate the expression level of sex steroid hormone receptors genes ($ER\alpha$, $ER\beta$, GPER, PRA, PRB, PGRmC1, mPR) in endometrial tissue and the peripheral blood mononuclear cells using RT-PCR.
- Dynamic monitoring of patients.

Personal data of patients will not be mentioned in work, publications, or reports.

Side effects and additions:

This study is safe and has minimal risk.

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