

# Medical Research Agency

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## The Medical Research Agency has begun work on an in-house project on early detection of endometriosis

Endometriosis is a condition that affects about 6 to 10% of women between the ages of 15 and 49. As experts estimate, the disease may affect up to 3 million women in our country. The main problem is the late diagnosis of the disease, after an average of 6-8 years of pain disabling women from normal functioning in society and from professional activity. The Medical Research Agency project is intended to address the challenge of the need for rapid diagnosis of endometriosis.

Endometriosis is characterized by the presence of endometrial cells (endometrium) outside the uterine cavity. These cells are still secretory active and, responding to hormonal changes during the menstrual cycle, cause a chronic inflammatory response in the body. In addition, endometriosis can also cause reduced fertility. More accessible diagnostics may be a lifesaver in the fight against the disease. Accordingly, the Medical Research Agency is working hard to launch a project to test the clinical utility of the EndoRNA test in a population of women with suspected endometriosis.

Until now, the only sure way to confirm endometriosis was through surgery - laparoscopy. The EndoRNA test, on the other hand, is an alternative for those women who want to be sure if they have endometriosis. The test is a short, safe procedure that can be performed in a doctor's office, involving the collection of a piece of mucous membrane during a gynecological examination. The EndoRNA test has been commercially available on the Polish market since 2023.

The EndoRNA test makes it possible to confirm or exclude the presence of endometriosis more quickly (the result even within 48h). Reduced diagnostic time is crucial for patients, as it allows them to start treatment earlier and minimize the negative effects of the condition. Statistics indicate that one in 10 women may suffer from endometriosis (up to 200 million women, WHO data), and not all cases are diagnosed. There is a need to increase awareness of endometriosis, both among patients and medical professionals. Improving recognition of the condition is key - endometriosis accounts for about 40 percent of female infertility and among endometriosis patients, 50 percent have a fertility problem. The EndoRNA test can be crucial in identifying cases that may have previously gone unrecognized, helping to improve endometriosis diagnosis statistics. What's more, it's a method that can be used in any doctor's office - it doesn't require specialized equipment, and the patient can return to her daily routine after taking the sample," stresses Lucyna Jaworska Wojtas - President of the Overcome Endometriosis Foundation.

The implementation of the ABM project will enable the clinical utility of the EndoRNA test to be tested against a population of patients with equivocal imaging findings or no imaging abnormalities despite clinical symptoms suggestive of endometriosis. An EndoRNA test will be performed on each patient, and the results will be compared with those from laparoscopy. The results of the experiment may be used by the Ministry of Health to order the Agency for Health Technology Assessment and Tarification

to evaluate the possibility of reimbursement for the test if results are received confirming its comparable effectiveness to laparoscopy.

In the event of a positive response regarding the test's comparable efficacy and sensitivity to laparoscopy, early detection of the condition and treatment will become possible. Early treatment is also a chance to reduce the consequences of complications accompanying advanced endometriosis.

Detecting different forms of endometriosis is crucial for personalized care and effective treatment planning, which can improve patients' quality of life. Other currently used markers like CA 125 or Bcl6 are not specific for endometriosis and do not clearly indicate the presence of the disease. My recommendation is to introduce the EndoRNA Test as an indication of endometriosis, but for proper diagnosis and treatment, Endometriosis Diagnosis and Treatment Centers must be established immediately and proper pricing of services introduced. This will then be a correct and comprehensive diagnosis and treatment to help the 3 million patients excluded from the health care system," concludes Lucyna Jaworska Wojtas - President of the Foundation to Defeat Endometriosis.

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