

INVICTA sp. z o.o. is a winner of the competition 'Research and development in the field of non-commercial clinical trials No. ABM/2020/1' and a beneficiary of financing agreement of 25 February 2021 with the **Medical Research Agency** for a non-commercial clinical trial project entitled '**Study of effectiveness of an oral drug containing Lactobacillus bacteria in achieving natural pregnancy in patients diagnosed with unexplained infertility**' (agreement no. 2020/ABM/01/00095-00). The state budget provides full financing in the amounts of PLN 1,446,378.00.

AIM OF THE PROJECT:

The aim of the project is to verify a research hypothesis regarding the impact of probiotics (Lactobacillus) on the endometrial microbiome and thus on the probability of pregnancy in couples with unexplained infertility, for which watchful waiting is recommended.

The study will involve 96 female participants randomly assigned to a group receiving a probiotic or a control group receiving placebo. Participants will take a probiotic or placebo during 6 menstrual cycles. The effects of the treatment will be assessed primarily based on the percentage of clinical pregnancies achieved in the compared groups.

In addition, in order to determine the indications for use and extend knowledge, the following will be assessed:

- percentage change in the share of Lactobacillus in the endometrial microbiome,
- thickness of the endometrium,
- endometrial receptivity (assessed in a biopsy),
- embryo implantation (based on beta HCG),
- live births before 37th week of pregnancy,
- live births in the 37th week and later.

Project schedule:

- organisation, registration, start-up (March – June 2021) – currently in progress
- phase of the proper study, i.e. recruitment for a non-commercial clinical trial and its performance – begins in July 2021 – we will provide information about it
- next stages – information will be given soon.



If you are interested in the trial or participation in the trial please, contact us at:
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