

ICMR to study efficacy of Metformin, Inositol in PCOS treatment

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New Delhi: India's apex health research body, ICMR, will undertake a study to evaluate the efficacy of two Polycystic Ovarian Syndrome (PCOS) drugs in improving fertility and birth outcomes among women

suffering from the ovarian condition. The drugs that have been recommended by experts for this purpose are Metformin and Inositol which are used in the treatment of the condition.

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Polycystic Ovarian Syndrome (PCOS) is a complex disorder ranging from mild to severe disruptions in reproductive, endocrine and metabolic functions, with key features including irregular menstrual periods (anovulation), hyperandrogenism, insulin resistance and abnormal gonadotropin secretion.

The prevalence of infertility in women with PCOS is high, varying between 70 and 80 per cent, the ICMR said in the EoI document.

Moreover, PCOS women have been found to have increased prevalence of pregnancy complications and less favourable pregnancy outcomes (live births, miscarriage, pregnancy rate) compared with women without PCOS, it stated.

In contemporary practice, the use of Metformin and Inositol for the treatment of PCOS is widespread.

"However, present evidence on the efficacy of these two drugs in terms of improvement in fertility and other related outcomes is insufficient," the ICMR said in a document.

A Finnish study suggested that, as compared to placebo, metformin improved the pregnancy rate, live birth rate and ovulation rate in the studied population, the document said.

However, a Cochrane review with meta-analysis including three other smaller studies reported that as compared with placebo, metformin may have only marginal benefit for live birth rate outcome.

Additionally, there is very limited data available globally on the effectiveness of Inositol for PCOS women, especially for birth outcome and cycle regulation.

"Evidence on the efficacy of both metformin and inositol in the Indian context is almost non-existent. To address the knowledge gap and to generate evidence on the management of PCOS for improving birth outcomes in the Indian context, the current ICMR call is being proposed," the document said.

The ICMR is looking to partner with interested researchers for the development of a multicentre randomised controlled trial for the management of PCOS in Indian women.

The selected researchers shall be invited to join the research team and shall collaborate to develop a full research proposal and roll out the multi-centre research project which will be coordinated by ICMR, the document said.

The research question is "Among women with Polycystic Ovary Syndrome (PCOS), how does inositol in comparison to metformin work in terms of efficacy and safety on outcomes including pregnancy conception, menstrual cycle regularisation, and improvement in endocrinological and metabolic parameters?"

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