

## **Abstract**

### **Background:**

Asthma is associated with reduced fertility and adverse pregnancy outcomes, However, the impact of biological therapies such as omalizumab on pregnancy rates remains unclear.

### **Methods:**

This randomised, double-blind, placebo-controlled trial investigated the effect of omalizumab on pregnancy rates in women with asthma undergoing in vitro fertilisation (IVF), with or without intracytoplasmic sperm injection (ICSI). Sixty-six women were randomised to receive either omalizumab or placebo during the follicular phase of the treatment cycle. End point of the study was pregnancy confirmed by transvaginal ultrasound at week 7-8 of gestation. Baseline characteristics, asthma control, and blood biomarkers were assessed. Changes in leukocyte count, total immunoglobulin E (IgE), and C-reactive protein (CRP) levels were analysed over time. Due to slow recruitment and a high dropout rate (42%), the study was terminated early, with only 66 out of a targeted 180 participants enrolled.

### **Results:**

A total of 31 participants completed the study (omalizumab: n = 18; placebo: n = 13). Pregnancy rates did not differ significantly between the omalizumab (72%) and placebo (62%) groups (p = 0.701). After the first treatment cycle, rates were comparable (33% vs. 46%, p = 0.470), with a non-significant trend toward higher pregnancy rates in the omalizumab group after the second cycle (39% vs. 15%, p = 0.237). Significant between-group differences were observed in leukocyte count (p = 0.016) and total IgE (p = 0.019), while CRP showed a significant change over time (p = 0.012). Pregnancy loss rates and other pregnancy outcomes, including preeclampsia, preterm birth, and caesarean delivery, were similar between groups. No cases of small-for-gestational-age (SGA) infants or congenital anomalies were reported.

### **Conclusion:**

Omalizumab did not significantly improve pregnancy rates or time to pregnancy in women with asthma undergoing fertility treatment. Nonetheless, the study provides reassuring evidence supporting the safety of administering omalizumab prior to conception. Given the limited sample size, larger trials are warranted to explore the potential effects of omalizumab and other biologics on fertility outcomes in women with asthma.