

TCS/23/19 - MAC-Endo: A proof-of-concept and feasibility study of macrophage-targeted immunotherapy in the management of endometriosis-associated pain

BACKGROUND: Endometriosis is a disease affecting 10% of women and those assigned female at birth. It is a condition where cells similar to those lining the womb grow elsewhere in the body ('lesions') and it can cause debilitating pelvic pain. Endometriosis can be treated by hormonal drugs, but only one third of women feel these are effective and many experience side-effects. In endometriosis, immune cells, called macrophages, become modified and encourage lesion growth.

AIM: In patients with endometriosis, we aim to investigate (1) the safety and side effects of RRx-001, an immune therapy designed to modify macrophages in cancer; and (2) the feasibility of a future large-scale UK-wide trial, to determine whether RRx-001 can reduce endometriosis-associated pain.

DESIGN AND METHODS: We plan to perform a study, called MAC-Endo, of 36 women with endometriosis pain, randomly assigned to receive once-weekly RRx-001 or identical placebo, for six weeks. Participants will complete questionnaires about their symptoms, give blood samples and have samples taken of their womb-lining. The information derived from the questionnaires and analysis of the blood and womb-lining samples will help us plan a future larger study to determine whether RRx-001 reduces endometriosis pain. We will interview 20 women to find out their feelings, views, and thoughts about all aspects of the trial.

DISSEMINATION: Trial results will be published in medical journals, presented at medical conferences, and publicised in summaries/infographics on social media platforms. The trial results will also be made available to patients on the Endometriosis UK website and social media.