Study Intervention

MAMA will compare two existing pathways of care for biologic use in pregnancy that are already being used in the UK, albeit with wide variation.

The two pathways of care being assessed are:

1. **Intervention**: continuing biologics throughout pregnancy.
   The woman's current biologic, dose and frequency of administration will continue.
2. **Comparator**: stopping biologics before the third trimester (week 28) of pregnancy and restarting no earlier than 2 weeks after the end of pregnancy.

For both groups, all other aspects of clinical care are determined by the treating clinical team.

Investigational Medicinal Product (IMP)

MAMA is an open label trial, healthcare teams and women will be aware of their allocation following randomisation. **All women entering into the study will already be taking biologics in their pregnancy, prescribed by their treating rheumatologist.**

The prescribed biologic will be taken from normal, non-trial stock and the standard NHS labelling for dispensed medicines will apply.

There is no requirement for pharmacy input, no changes to existing prescriptions or dispensing of medication. We do not require trial accountability logs to be completed.

Dosage

The drug, dose and frequency of administration of a woman's biologic is at the discretion of the prescribing clinician, and all other aspects of clinical care are determined by the treating clinical team.

Crossover between Allocated Care Pathways

Crossover will be captured by **woman self-report** using the MAMA app or paper diaries. Reasons for missed doses if allocated to continuing treatment, or doses taken if allocated to stopping treatment, will also be captured (e.g., patient decision, forgot, advised to miss dose in setting of infection, etc.).

Crossover will be defined as:

For the continuing biologic allocation: Reported as missing all doses of bDMARD between 28 weeks of pregnancy until 2 weeks after the end of pregnancy unless clinically indicated;

For the stopping bDMARD allocation: Reported as taking at least one dose of bDMARD between 28 weeks of pregnancy until 2 weeks post- pregnancy unless clinically indicated.

Escalation of therapy for worsening disease would not be considered crossover for either trial arm.

GUIDANCE SHEET 6