Screening and Eligibility

GUIDANCE SHEET 3

Participant identification

Identification of potential participants may be through referral letters, maternal medicine antenatal clinics, maternity booking appointments, general antenatal clinics or rheumatology services. Anyone involved in the study can support identification of participants but final assessment of eligibility must be carried out by appropriately trained and experienced doctors, nurses, and midwives as delegated by the Principal Investigator.

Co-enrolment

Co-recruitment of participating women to other non-interventional studies would generally be permitted. Co-recruitment to another Clinical Trials of Investigational Medicinal Products (CTIMP) must be agreed between Chief Investigators.

Please contact the MAMA Study Team with details of any new CTIMPs where co-enrolment is a possibility to facilitate early discussion and agreement.
If co-enrolment is not permitted we ask that women are offered any studies that they may be eligible for (at the same time) so that women can choose which, if any, they wish to participate in.

Pre-pregnancy approach

Some women will consider whether to stop biologics when planning a pregnancy. Incorporating the opportunity for pre-pregnancy discussions could give more women the opportunity to participate in the trial.

The **MAMA (Preconception) Information Leaflet** contains information for women who may be planning pregnancy and are currently being treated on a biologic for inflammatory arthritis.

Rheumatology services: Although women will not be recruited directly from rheumatology departments, engagement of rheumatologists and specialist rheumatology nurses is important for successful recruitment to the trial.

Brief information about the trial will be provided widely at rheumatology clinics and through rheumatology nurse specialists to women of child-bearing age, informing them about the trial in the form of **posters, banners** and **Preconception Information Leaflets**.

This will allow women the opportunity to discuss the trial before they become pregnant, and to consider the trial in the context of any pre-pregnancy discussions about medication choice during pregnancy.

Potential participants may be given information about the study, but confirmation of eligibility and consent must be taken **after** the woman becomes pregnant (please refer to eligibility criteria). Women potentially meeting the eligibility criteria should be screened for eligibility by their clinical care team at the recruiting site.

Referral pathways

Women can be directed to recruiting sites in several ways:

- A woman who has discussed the trial pre-pregnancy may contact a recruiting site directly once she becomes pregnant.
- A woman may be referred to a recruiting site as part of the Maternal Medicine Network referral pathway; this could be for clinical advice or obstetric care.
- A woman might be being cared for directly by the recruiting site.
- A woman may contact the MAMA Trial Team directly, e.g. where women have heard about the trial but are not at a recruiting site for their care. The trial team will direct women to a local recruiting site.

Eligibility

Since the MAMA eligibility criteria does not require specific medical evaluation, assessment of eligibility can be performed by staff at the recruiting site who are:

- Appropriately trained and experienced doctors, nurses, and midwives (as documented on the **MAMA Training Log**)
- Delegated by the Principal Investigator to **Confirm Eligibility** (as documented on the **Site Delegation Log**).

The eligibility criteria are as follows:

Pregnant women with Autoimmune Inflammatory Arthritis (AIA), satisfying the following criteria:

Inclusion criteria

- Have a diagnosis of rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA) or axial spondyloarthritis* (axSpA)
- Pregnant at less than 28 completed weeks' gestation
- Prescribed one of the following regularly dosed biologics (including the listed reference medicinal product and biosimilars) for RA, JIA, PsA or axSpA;*sometimes called ankylosing spondylitis

Class of drug	bDMARD
Biologic drugs which block Tumour necrosis factor (TNF)	Humira and biosimilars Active ingredient: Adalimumab
	Enbrel and biosimilars Active ingredient: Etanercept
	Remicade and biosimilars Active ingredient: Infliximab
	Symponi and biosimilars Active ingredient: Golimumab

	Cimzia and biosimilars Active ingredient: Certolizumab pegol
Biologic drugs which block CD80/86	Orencia and biosimilars Active ingredient: Abatacept
Biologic drugs which block Interleukin 6	RoActemra and biosimilars Active ingredient: Tocilizumab
	Kevzara and biosimilars Active ingredient: Sarilumab
Biologics which block interleukin 1	Kineret and biosimilars Active ingredient: Anakinra
	Ilarus and biosimilars Active ingredient: Canakinumab
Biologics which block interleukin 17	Cosentyx and biosimilars Active ingredient: Secukinumab
	Taltz and biosimilars Active ingredient: Ixekizumab
	Bimzelx and biosimilars Active ingredient: Bimekizumab
Biologics which block interleukin 23	Tremfya and biosimilars Active ingredient: Guselkumab
	Skyrizi and biosimilars Active ingredient: Risankizumab
Biologics which block interleukin 12/23	Stelara and biosimilars Active ingredient: Ustekinumab

- Aged 16 years or over
- Has provided informed consent

Exclusion criteria

- Prescribed rituximab either during pregnancy or in the 6 months prior to conception
- Prescribed JAK inhibitors
- Contraindication to stopping bDMARDs (e.g. active, sight-threatening uveitis)
- Current, active tuberculosis in the immediate or close family or household members
- Plans to move in the first 6 months after birth with their infant to live in a country with a high rate of tuberculosis (incidence >40 per 100,000 population)

Enter all women screened on to the **MAMA Screening Log**.

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Screening Log

A record of all women screened should be maintained at site on the **MAMA Screening Log**. Please include all women screened, even if the woman is not approached or declines participation.

Please complete a row on the **MAMA Screening Log** for all pregnant patients who are:

- At less than 28 weeks of gestation at first point of contact with your site
  AND
- Prescribed a regularly dosed biologic DMARD (bDMARD) for:
  - Rheumatoid arthritis
  - Juvenile idiopathic arthritis
  - Psoriatic arthritis
  - Axial spondyloarthritis (sometimes called ankylosing spondylitis)

A paper version of the **MAMA Screening Log** is available in the MAMA Document Box. A blank printable electronic copy is included in the **electronic Investigator Site File** (eISF). Paper logs are not expected to be submitted back to the MAMA Study Team, these can be filed locally in the site folder included in the Document Box.

Uploading Screening Log data

Once a month, enter summary data for those screened on the MAMA Randomisation Website by visiting **https://rct.npeu.ox.ac.uk/mama**, logging in and choosing the screening log option.

You will login to the MAMA Randomisation Website using an invividual NPEU account login. Contact the MAMA study if you require assistance logging in.

Please note that participants who were randomised to MAMA will have been automatically added to this electronic screening log. Please update their entry on the electronic log with where they first heard about MAMA.

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This study is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme (Reference Number NIHR153577).
The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.