count, neutrophil count, platelet count, alanine transaminase (ALT) level, aspartate transaminase (AST) level, and creatine level will be recorded in the CRF. Additional results of concern should be reported as adverse events as per Section.

See section 7 "Trial Treatment and Regimen" for further details on the data collection timepoints.

Stopping rules and discontinuation

The Sponsor reserves the right to discontinue this trial at any time for failure to meet expected recruitment targets, for safety or any other administrative reasons. The Sponsor shall take advice from the TSC and the funder (NIHR HTA) as appropriate in making this decision.

Study Within A Trial (SWAT)

A SWAT will be embedded into the trial to investigate whether inclusion of a trial information video (available via QR code or URL) within the Participant Information Sheet (PIS) with trial information increases recruitment over a PIS without the link. Sites will be randomised to one of the following:

- Intervention Group 1: PIS with QR code to information video
- Intervention Group 2: Standard PIS

Randomisation will take place prior to the specified site's Site Initiation Visit (SIV), using a web-based randomisation system developed and maintained by the Nottingham Clinical Trials Unit (NCTU) and hosted on a secure server, accessed via a secure website.
The video topics were suggested by our patient advisory group and will include information on what the MOOSE trial is about, a summary of what participation involves, the value of participation, and the next steps to take if considering joining the trial. There will also be a section on how to take methotrexate in subcutaneous forms. The video will be embedded in the REDCap database, to allow the number of times the video has been viewed to be recorded.

The primary outcome will be the proportion of patients given a PIS who are consented at each site.
The secondary outcomes will include the proportion of participants providing primary outcome data (at 24 weeks), and the proportion of participants remaining in the trial at 52 weeks.

It is planned that interim analyses comparing the proportions of participants consenting in the two intervention groups (those with PISs with the QR code to the information video and those with PISs which do not have the QR code) will be performed at 9 and then potentially at 15 months after the first participant is randomised to determine whether there is a greater proportion consenting in either of the intervention groups.

Where there is a notable difference in consent rates (such a difference will be defined in the SAP for the SWAT) at 9 months, the PIS which is associated with the higher consent rate will be adopted for the remainder of the trial. If there is no difference, an additional interim analysis will be performed at 15 months. If a notable difference is observed at this point, the PIS which is associated with the higher consent rate will be adopted for the remainder of the trial. If there is no notable difference observed, the trial will continue recruiting to the end using both PISs.