

Frequently Asked Questions

Patient Eligibility Questions

[Open all sections](#)

Q - Are there any steroid medications that are permitted for the trial only?

A - Patients currently taking steroid medications administered systemically including oral tablets and IV steroids are NOT eligible for DREAMS. Patients taking locally delivered steroids including eye drops, topical cream, inhalers or suppositories are eligible for the trial.

Q - If a patient has been on a course of steroids how long do they have to have finished the course to be eligible?

A - A patient has to have finished a course of steroids for a period of 3 months to be eligible to enter the DREAMS trial.

Q - How should an acute gastric ulceration be confirmed?

A - For the DREAMS trial this must be confirmed by an endoscopy.

Q - Are HIV immune suppressant patients eligible?

A - No, they are not eligible.

Q - Can a patient enter the trial twice if they are having a second operation i.e. reversal of stoma?

A - No, a patient can only participate in the DREAMS trial once.

Randomisation Questions

Q - If a patient is not having an Epidural or Patient Controlled Anaesthesia how is this recorded at randomisation?

A - A third option of 'other' will be added to this question on the Randomisation Notepad.

Q - What information do you require from site before randomisation takes place?

A - Prior to randomisation, we require a list of full names and work email addresses so that they can be added to our online database before the procedure. These include: Responsible Clinician, anaesthetist, surgeon, consenting clinicians and the person randomising (anyone named on the randomisation notepad).

Consenting clinicians need to forward signed copies of their current GCP certificate and CV to the BCTU trials office as well as ensuring they are recorded appropriately on the delegation log before consenting patients into the trial.

During the randomisation process, all the patient-related information we require is present on the form and should be filled out in advance of contacting the BCTU trial team to randomise in order to make sure that the randomisation process goes smoothly.

Q - Can the patient be told what allocation they received whilst on the DREAMS trial?

A - No, the patient cannot be informed of their allocation until the end of the trial.

Case Report Form Questions

Q-How many days leeway do we have on CRF completion at the various time points?

A - For the Day 1, 3 and 5 forms these have to be completed on the exact days within 2 hours either way of when the operation occurred. For instance if the operation took place at 3pm on a Friday then the Day 1 form will have to be completed 2 hours either side of 3pm on Saturday.

For the Day 30 questionnaires, there is a maximum of a 2 days window either side of the time points required.

Q-For the Day 30 questionnaires can these be done over the telephone?

A - The trial protocol asks that patients complete their Day 30 questionnaires face-to-face. This is because it is important that their wound is properly assessed, since this forms part of the data collected for the DREAMS trial. However if this is not possible, patients can be contacted over the telephone as a back-up option.

Q-What do I do when I am running low on patient CRF packs?

A - We supply printed and collated CRF packs to sites, so if your site runs out please [contact us](#) ([/research/activity/mds/trials/bctu/trials/coloproctology/dreams/contact.aspx](#)) to ask for more.

If copies are required immediately at the site, then they can be downloaded online and printed off from [here](#) ([/research/activity/mds/trials/bctu/trials/coloproctology/dreams/investigators/documentation.aspx](#)). Alternatively sites are emailed CRF packs when they first open so they can be obtained that way.

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