STOP'EM FAQs for Sites

Q1. What is a 'newly-diagnosed' meningioma?

A1. Any participant undergoing their first surgery for meningioma can be considered including:

- Incidental meningioma that has grown and needs surgery
- Recent diagnosis of symptomatic meningioma

Q2. Is the inclusion criterion on meningioma diagnosis limited to Grade 1, or does it account for Grade 2 and 3?

A2. Any meningioma will have surgery – the grade will only be known after surgery, so patients stay on the trial regardless of grade 1, 2 or 3.

Q3. If the participant requires radiotherapy (RT) or stereotactic radiosurgery (SRS) treatment post-surgery, are there any contraindications or guidelines whilst the participant is in the follow-up period?

A3. The participant should stay on trial, even if they subsequently have RT or SRS.

Q4. Is there an ideal timeframe for randomisation?

A4. Randomisation can occur once all baseline assessments are completed (e.g., a patient may consent to join the trial soon after their diagnosis, but baseline & randomisation may not occur until the pre-op appointment). Ideally, you would randomise close to the date of surgery (e.g., at the pre-op appointment).

Q5. What is the format of the screening number?

A5. The screening number will consist of a 3 digit site code and 3 digit sequential screening number (sequential per site).

Q6. What is the format of the randomisation number?

A6. The randomisation number will begin with the letter 'R' followed by a 3 digit site code and 4 digit sequential randomised number (sequential across the trial)

Q7. What happens if surgery is cancelled, and the participant has already started IMP?

A8. Sites will be provided with extra supplies of bottle A in case the participant's surgery is delayed/ participant attends for surgery but does not bring medication with them and re-dispensing needs to occur. Participants should remain on the trial.

Q9. What happens if a participant has a seizure in the first 2 weeks?
A9. Unblinding can occur in the event of an emergency, or if participant experiences post-operative seizures within the first 2 weeks of surgery. Clinician at recruiting site will contact their local pharmacy team to unblind:

- Participant should be treated as if they had received levetiracetam
- Sites should use local treatment protocols e.g., 1g phenytoin, LEV 750mg bd etc.
- If Pharmacy are unavailable to unblind out-of-hours, unblind as soon as possible

Reminder: any participants that are unblinded should remain in the trial and follow-up continued as per protocol.

Q10. What if a participant wants to know what their treatment allocation was?
A10. Sites can only provide this information at the end of the trial (after database lock).

Q11. Can we do telephone instead of video / face-to-face clinics?
A11. The protocol allows for telephone follow-up for visits 3 and 4. We appreciate that COVID has changed how we deliver clinics; sites should exercise judgment in the use of telephone, video or face-to-face for clinic visits for each participant.

Q12. How do we monitor for seizures?
A12. Participants will be given a checklist of symptoms to look out for – this is on the back of the contact card. As well as this, Research Nurses will use an aide memoir of questions to ask at each visit.

Q13. What do participants do if they have a seizure?
A13. The trial participant (patient) should be reviewed by the neurosurgery team to confirm the diagnosis of seizures. If there is uncertainty about the diagnosis of seizures, an assessment by a neurologist is required (as per normal clinical pathways).

Q14. Will PDF eCRFs be provided?
A14. PDF eCRFs should be accessed via REDCap by sites teams. You should download and print paper copies of these eCRFs as a back-up.

Q15. Can we administer questionnaires remotely?
A15. During face-to-face visits, paper questionnaires should be used – the participant will complete these, site will transcribe data onto REDCap and file the wet-ink source documents in the ISF.

During video consultations, paper questionnaires will be used. However, the researcher/interviewer will complete these by recording participant responses. Again, site will transcribe data onto REDCap and file the wet-ink source documents in the ISF.