A pragmatic randomised controlled trial comparing the effectiveness and cost-effectiveness of levitiracetam and zonisamide versus standard treatments for epilepsy: a comparison of Standard And New Antiepileptic Drugs

TRIAL RECRUITMENT NEWS

- We are **HALF-WAY** to achieving the trial recruitment target! Wooo-hoooo!
- **LIVE recruitment figures** (updated daily) are now on the trial website, under *Recruiting Centres* tab.
- The next substantial amendment to trial protocol is in preparation. It will include new sites and revised patient questionnaires.
- We have opened 86 sites since the trial commencement in June 2012 and we have about 10 more to open to reach our target.
- We are **still open to new sites**. Get in touch, if you want to take part.
- It is the Principal Investigator's responsibility to ensure site team members are appropriately trained to work on the trial. New site staff could also attend one of the trial office-led webinars. Get in touch, if you need to attend a training webinar.
- Are you working on the current **versions** of trial documents? You can request a list of all current versions from the trial office.
- **Thank You for the fantastic recruitment and continuous support!**

CONTACTS

SANADII Trial Office
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PATIENT CONTACT DETAILS

- ✓ Patient contact details are collected on **Form 2**.
- ✓ Patient contact details are needed for questionnaires distribution.
- ✓ Patient telephone number completion is essential.
- ✓ Submit photocopy of Form 2 for every patient recruited.
- ✓ Post completed Form 2 in a separate envelope from other forms.
- ✓ All trial documentation should be submitted **within 7 days** from the patient visit, as per trial protocol.
- ✓ Submit updates to Form 2, when needed.
- ✓ **Patient questionnaires'** completion is monitored by the trial office. Issues with non-compliance are highlighted with the sites and their assistance is required.

REMINDERS

- ✓ **Adverse Event whose causal relationship to the randomised study drug or other anti-epileptic drug assessed by the investigator as "possible", "probable", or "almost certainly" is classed as an Adverse Reaction (AR) and is reportable for SANADII (see protocol section 10.5).**
- ✓ **Adverse Reactions** described on version 1 of the form should be resolved on the same form, while any new adverse reactions should be entered on the updated version 2. If unsure, email trial office.
- ✓ **Investigations form 4** should **only** be completed for investigations (EEG, MRI and CT) related to determining the epilepsy type at the trial commencement. You should only complete and submit when you have the results.
- ✓ **Please check** that for every collected DNA sample, you have completed a **DNA form**.
- ✓ **Re-supply** requests should be done via email. Please include the quantities, your delivery address and a recipient name.

The SANADII Study is funded by the NIHR HTA Programme , and is being run from the Liverpool Clinical Trials Research Centre.