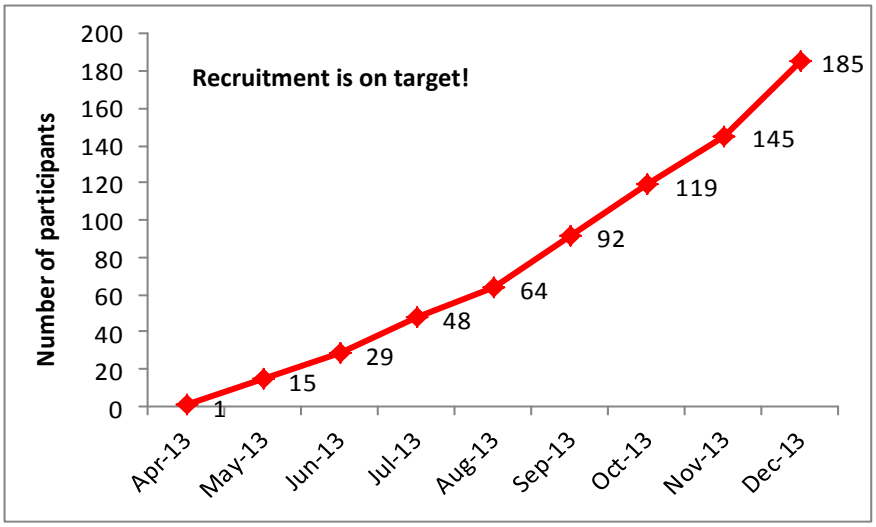
A pragmatic randomised controlled trial comparing the effectiveness and cost-effectiveness of levitiracetam and zonisamide versus standard treatments for epilepsy: a comparison of Standard And New Antiepileptic Drugs (SANAD-II)

TRIAL RECRUITMENT



SITES OPENED IN DEC*

Site	Service	PI
Diana Princess of Wales Hospital, Grimsby	Paediatric	Dr Al-Moasseb

*If you want to know which sites are already on board, check the SANADII website www.sanad2.org.uk. A total of 48 sites have been opened to recruitment as of end of Dec 2013 .

FREQUENTLY ASKED QUESTIONS

Can we recruit to Arm A only?

Yes.

Can we recruit to Arm B only?

Yes.

Can we fax consent forms?

No. Please refer to initiation training presentation for details.

When do we collect the DNA sample?

At the baseline visit or at the first follow-up visit, preferably.

Where is the baseline questionnaire completed?

At the patient's home.

Do we ask the participants to attend the clinic at 3, 6 and 12 months and annually until end of trial?

Patients will be followed up as per routine clinical practice, typically at 3, 6 and 12 months and annually until end of trial.

CONTACTS

Trial Manager
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REMINDERS

- ✓ Complete the header on the front cover of the baseline questionnaires before issuing.
- ✓ Post a photocopy of the Consent Form to the trial office.
- ✓ Post the original DNA CRF form to the trial office.
- ✓ Use the **current approved CRF forms & versions**: form 1 Ver2, form 2 Ver3, form 4 Ver1, form 5 Ver2, form 6 Ver1, form 7 Ver1, form 8 Ver2, Adverse Reaction form Ver1, form 11 Ver1 and Serious Adverse Reaction form Ver2. Please make sure you have them at site. All previous versions should be marked as superseded. Let us know if you do not have them and we will re-supply.

The SANADII Study is funded by the NIHR HTA Programme, and is being run from the Liverpool Clinical Trials Research Centre (for more details see www.ctrc.co.uk).