



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

Recruitment during June and July has been fantastic. In July we enrolled 58 patients, which is the highest ever for the trial.

Don't forget to keep an eye on the LIVE recruitment figures, displayed on our website <http://www.sanad2.org.uk/centres.html> and updated daily.

Our office team is always available to answer your queries including about randomisation process and DNA sampling.

We would like to Thank you All for the great support and dedication.

Have a great remaining of the summer!



PAEDIATRIC RECRUITMENT

A message from Prof Tony Marson (Chief Investigator) and Dr Richard Appleton (Coordinating Investigator for paediatric sites)

The rate of recruitment of children (<16 years) continues to be encouraging, particularly in Arm B (generalised and unclassified). The rate of recruitment in Arm A has fallen somewhat in the past 3 months and it would be fantastic if investigators could double or even triple their efforts to approach and recruit some more patients.

As a reminder, the scientific and ethical basis of randomised controlled trials (RCTs) such as SANAD II is about equipoise, where the clinician and patient have no clear preference for any of the treatment options in the trial. Consequently, please would you try and recruit all patients you see where this equipoise exists. Patients (of any age) should not be recruited and randomised if the investigator or patient do not have this equipoise.

SUBSTANTIAL AMENDMENT 7



- ✓ Submitted to ethics on 31st July 2015 (30-day review period)
- ✓ Submitted to MHRA on 31st July 2015 (30-day review period)
- ✓ Uploaded to CSP on 31st July 2015 for your local R&D department to receive, review and approve (please let them know, if they haven't noticed)
- ✓ New sites and changes to sites were approved by REC on 3rd Aug 2015 (REC approval to be emailed to sites shortly)
- ✓ SA7 involves revised patient questionnaires
- ✓ SA7 involves update to patient information sheets
- ✓ SA7 involves minor edits to protocol, summarised, as usual, at the end of the document

SANADII Trial Office

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