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

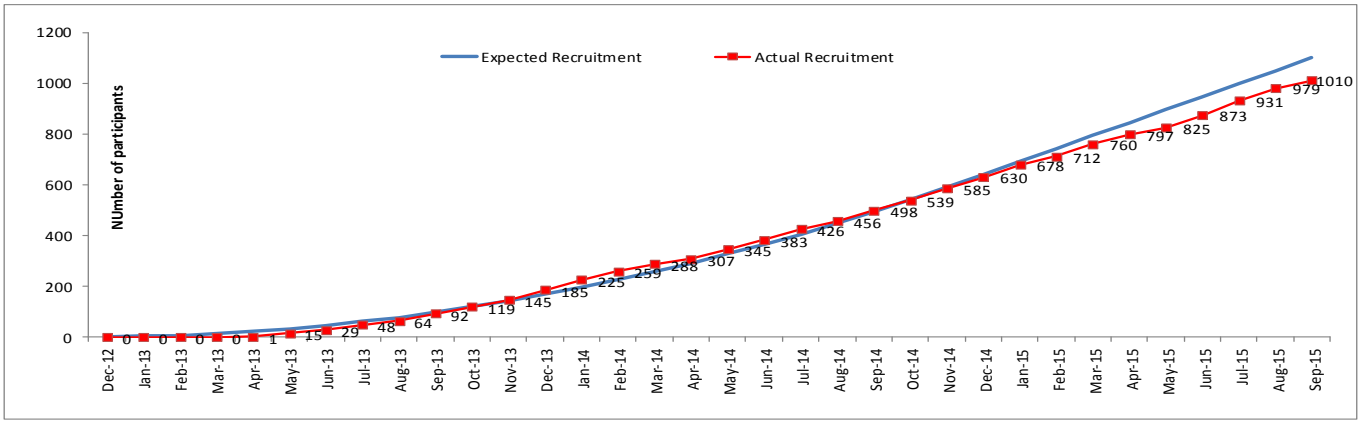
Trial recruitment in August was great! On the 18th September SANADII trial recruited patient No.1000, which means we are more than half-way through our trial target recruitment. Woo-Hoo!

With only about a year left to recruit the remaining patients we will be approaching sites for revised recruitment targets shortly. In England this will be coordinated through the Clinical Research Network and your local portfolio delivery managers for neurology. For Wales, Scotland and Northern Ireland sites have been already contacted by the trial office and replies are collated. Your replies are important, because they will inform trial's management team discussion about site setup and recruitment timeline.

Don't forget that LIVE recruitment figures are 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.

Thank you (again) for the continued support and dedication!



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

- ✓ **Substantial Amendment 7 (SA7)** was approved by ethics and MHRA, and the 35-day window for local R&D approval has lapsed in the beginning of September.
- ✓ Trial office has commenced distribution of the **new and updated documentation** via email to all sites.
- ✓ SA7 involves **revised patient questionnaires**, which will replace the existing.
- ✓ SA7 involves **amended patient information sheets and consent**, which will replace the existing.
- ✓ The **new consent form** will be used for future patients only. It will not be applied retrospectively to previously consented patients and no re-consenting is requested or required.
- ✓ SA7 includes new **CRF Form 13 Ethnicity**, which should be completed by the patient donating DNA.
- ✓ SA7 involves minor edits to **protocol**, summarised, as usual, at the end of the document on page 63.

CONTACTS

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