# A multicentre, randomised, controlled, clinical Investigation of a standalone decision support Algorithm for Neonatal Seizure Recognition

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Seizures (incl subtypes) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON44340

**Source**
ToetsingOnline

**Brief title**
ANSeR

### Condition

- Seizures (incl subtypes)

**Synonym**
convulsions, fits

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** University College Cork, National University of Ireland

**Source(s) of monetary or material Support:** Wellcome Trust;Verenigd Koninkrijk

## Intervention

**Keyword:** Algorithm, Neonates, Seizure Detection Tool, Software

## Outcome measures

### Primary outcome

Diagnostic accuracy of investigation personnel with and without the use of the ANSeR Software System in routine clinical practice for a minimum of 2 hours up to maximum of 100 hours of post-natal EEG monitoring, using an expert panel as the reference standard.

### Secondary outcome

The following secondary endpoints will be used to determine the impact of the ANSeR Software System.

(1) The number and duration of all electrographic seizures will be quantified to measure seizure burden in both groups. Electrographic seizures will be determined by the expert EEG committee.

(2) The number of AEDs administered in both groups will be compared. The timing of administration will be correlated with on-going electrographic seizure activity in each group to determine the appropriateness of AED administration

# Study description

### Background summary

Seizures are the most common neurological emergency encountered in the neonatal intensive care unit (NICU) and are the hallmark of neonatal encephalopathy.

Despite this they remain difficult to diagnose clinically.
Electroencephalography (EEG) monitoring is the gold standard for seizure detection but real-time interpretation is challenging for most in the acute setting.
Neonates can have peculiar movement patterns that are not associated with any EEG *signature* of seizure. Alternatively, continuous EEG monitoring can show status epilepticus in neonates who have little, if any, clinical manifestations. The occurrence of *electro- clinical dissociation* - what you see is not what you get- is a particular problem in neonates. In this group, 80-90% of electrographic seizures are *EEG-only* seizures. We have previously shown that only 9% of the time-summed total seizure burden in a group of 51 neonates was accompanied by clinical manifestations.
The accurate diagnosis of seizures matters a great deal. Research suggests that *seizures beget seizures* and those seizures contribute to neuronal damage in neonates with hypoxic ischaemic encephalopathy. In clinical practice, many neonates are treated on the basis of clinical diagnosis alone and this may result in both under treatment and over treatment (because small normal movements are misinterpreted as seizures). Over treatment carries the risk of extending the duration of ventilation and intensive care stay, and increasing the neurotoxic effects of antiepileptic drugs.
All experts agree that there is an urgent need for an accurate and robust method of seizure detection, which can provide information in a readily digestible form, in real time at the cotside. Translating automated seizure detection from the bench to the cotside is challenging, and has not so far been achieved.

## Study objective

The primary objective of this investigation is to assess the performance of the ANSeR Software System by quantifying and comparing the diagnostic accuracy of investigation personnel using the ANSeR Software System with the diagnostic accuracy of investigation personnel not using the ANSeR Software System for the diagnosis of neonatal seizures. The Expert Committee will be used as the diagnostic reference standard. The secondary objectives are to quantify and compare seizure burden and AED use in the algorithm group and non-algorithm group.

## Study design

This will be an open, two arm, parallel group, randomised, controlled investigation of the ANSeR Software System as a stand-alone neonatal seizure recognition decision support tool. Term neonates requiring EEG monitoring will be stratified by recruiting site and then randomised to receive either EEG monitoring with the ANSeR Software System or EEG monitoring without the ANSeR Software System.

### Intervention

EEG monitoring with the ANSeR Software System as a seizure detection algorithm.

### Study burden and risks

Neonates randomised to the control arm of this investigation will receive standard clinical care and continuous EEG monitoring as per protocols at the local sites. There is no additional risk envisaged in this group.*Neonates randomised to the active arm will receive standard clinical care and continuous EEG monitoring with the support of the ANSeR Software System. The ANSeR software analyses EEG data that is collected as normal standard of care and emits a continuous output of the ANSeR Seizure Detection Algorithm at the cot side in real time. The ANSeR Software System does not provide any diagnostic conclusion.
Treatment of any seizures identified by the investigation personnel in both arms of the investigation will be as per local procedures and guidelines.*The hypothesis is that the diagnostic accuracy of neonatal seizures will improve when the ANSeR Software System is available to alert healthcare professionals to potential seizures and inform the diagnostic decision. Real-time continuous assessment of the aEEG with a maximum of two channels is standard clinical care in our center. Detailed assessment of a multiple-channel EEG is performed retrospectively at this moment. Therefore, we would expect an improvement in the accuracy of seizure detection in neonates randomised to the active arm. This may lead to improved appropriateness and promptness of the AED treatment regime.

A retrospective study of 300 paediatric and adult patients indicated that continuous monitoring of EEG could lead to a change in AED administration in 52% of patients included in the study. While this figure is startling it should be remembered that in neonates, the clinical indications of seizures are often not present or are more subtle in comparison to those seen in the adult or paediatric population making identification of seizures even more difficult in neonates.
The potential benefits of being randomised to the ANSeR Software System outweigh the risks. It is anticipated that the ANSeR Software System will be safe for use and will provide accurate information to assist in seizure diagnosis, which is to the benefit of the neonate and the healthcare system.

## Contacts

### Public
University College Cork, National University of Ireland

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**Scientific**
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Children (2-11 years)

## Inclusion criteria

Neonates 36-44 weeks corrected gestational age in whom EEG monitoring is indicated because they are deemed to be;
- at high risk of seizures,
or
- are experiencing seizures

## Exclusion criteria

No parental/guardian consent

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Diagnostic

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 29-06-2015 |
| Enrollment: | 40 |
| Type: | Actual |

## Medical products/devices used

| | |
|---|---|
| Generic name: | ANSeR Software System |
| Registration: | No |

# Ethics review

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| Approved WMO Date: | 19-03-2015 |
| Application type: | First submission |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |

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| Approved WMO Date: | 16-02-2016 |
| Application type: | Amendment |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL50893.000.14 |