

# Phase 1 study of use of 5% Carbogen in treatment of paediatric nonconvulsive status epilepticus

<b>Submission date</b> 17/05/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 17/05/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 12/12/2017	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Non-convulsive status epilepticus (NCSE) happens in some kinds of childhood epilepsy. 'Status epilepticus' means continuous seizure activity. There are two kinds of status epilepticus. The common kind is known as convulsive status epilepticus. In this kind the seizures are very obvious to anyone watching. The other kind is called non-convulsive status epilepticus (NCSE) and is rarer. In NCSE there are few signs of a seizure although brain wave (electroencephalography [EEG]) recordings show that continuous seizure activity is happening. During NCSE what tends to be noticed is that a child is less responsive, drowsier or in some other way not as alert as usual. NCSE happens in a number of different childhood epilepsies and can be a recurring problem. Convulsive status epilepticus (the kind with externally obvious seizures) requires prompt medical treatment. NCSE is less of a medical emergency. There is no clear evidence that NCSE causes brain damage. Many of the current treatments for status epilepticus are sedating and repeated use of these medicines during a period of NCSE can cause additional problems such as chest infections or even a need for support on a breathing machine. We are running this study because we are looking for better treatments for NCSE. In this study we are testing whether breathing a medical gas called Carbogen for a short time is tolerated and whether it has any beneficial effects in treating NCSE.

### Who can participate?

Children aged 0-16 with an established diagnosis of epilepsy of symptomatic or presumed symptomatic (cryptogenic) origin, in electrographically proven NCSE, admitted as inpatients for control of NCSE

### What does the study involve?

If an EEG confirms NCSE in a child, they will breathe a 5% carbogen mixture by a face mask held over the mouth and nose with a gentle elastic strap. This will happen in the EEG department, and with the EEG still being recorded. The period of inhalation may change during the period of the trial in light of early experience. The inhalation will initially be for a period of 2 minutes (120 seconds): if it turns out that the first children involved in the study tolerate this well, it may be increased up to absolute maximum of 6 minutes. If it turns out that the first children involved in

the study do not tolerate this well, the period will be shortened. Then the mask will be removed and your child will breathe room air as normal. We would continue to record the EEG for another 20 minutes and will study whether the EEG improves at all after breathing carbogen.

What are the possible benefits and risks of participating?

Carbogen is a mixture of two of the gases found in normal air and breathing carbogen is similar to re-breathing exhaled air (e.g. from a paper bag). Carbogen is already used in a number of other medical treatments and is a safe and well tolerated treatment. Breathing higher concentrations of carbogen than we are using in this study causes an urge to breathe (similar to that experienced if you hold your breath for a long time) which is unpleasant and can cause a sense of panic. But in the same way as this feeling goes away quickly once you start breathing normally again after holding your breath, it goes away rapidly as soon as carbogen inhalation is stopped. There may be no direct benefit to the child from taking part. The primary aim of this study is to see whether carbogen inhalation is well tolerated and acceptable but we are also interested in its usefulness as a treatment for NCSE. This may reduce the need for the child to receive other treatments but as yet this is not known.

Where is the study run from?

This study is being run in Newcastle and Manchester (UK)

When is the study starting and how long is it expected to run for?

Recruitment will start in June 2012 and will run for 2 years

Who is funding the study?

Epilepsy Research UK

Who is the main contact?

Dr Rob Forsyth (Chief Investigator and study lead in Newcastle)

## Contact information

### Type(s)

Scientific

### Contact name

Mr Chris Speed

### Contact details

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## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

12223

## **Study information**

### **Scientific Title**

Phase 1 study of use of 5% Carbogen in treatment of paediatric conconvulsive status epilepticus

### **Acronym**

CONCEPT

### **Study objectives**

Phase 1 study of use of 5% Carbogen in treatment of paediatric non-convulsive status epilepticus

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

North East - Sunderland Research Ethics Committee, 13/04/2012, ref: 12/NE/0005

### **Study design**

Non-randomised interventional trial

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised study

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Status epilepticus

### **Interventions**

The intervention comprises administration of 5% carbogen by spontaneous inhalation administered via a loosely attached face mask (flow rate 5l/min) for a period stipulated by the protocol (timed by hand-held digital stopwatch).

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Four five-minute epochs of EEG will be excerpted for each patient. 5 mins prior to inhalation and 0-5, 5-10 and 10-15 minutes after completion of inhalation.

**Secondary outcome measures**

1. Assessment of safety
2. Capillary blood gas pH

Measured at the end of the period of inhalation

**Overall study start date**

19/01/2012

**Completion date**

19/01/2014

**Eligibility****Key inclusion criteria**

1. Child under 16 with known epilepsy (i.e. established tendency to recurrent seizures)
2. Aetiology of epilepsy known, or investigation deemed sufficient to infer a cryptogenic (presumed symptomatic) epilepsy
3. No clinical suspicion of current episode being associated with acutely raised intracranial pressure
4. Confirmed non-convulsive status epilepticus on EEG defined as the presence of
  - 4.1. Bihemispheric
  - 4.2. Continuous or near-continuous
  - 4.3. Spikewave or other features indicative of seizure activity
  - 4.4. History from parent, or other experienced carer familiar with the patient, of lower level of awareness than normal
5. Note that the presence of subtle continuing clinical seizure activity is not an exclusion criterion so long as the treating physician is satisfied that urgent treatment is not required.
6. Informed consent provided by parent/legal guardian

**Participant type(s)**

Patient

**Age group**

Child

**Upper age limit**

16 Years

**Sex**

Both

**Target number of participants**

UK Sample Size: 30

**Key exclusion criteria**

1. Age > 16 years
2. Absence of informed consent from parent/legal guardian
3. Evidence of prior chronic respiratory disease and/or type 2 respiratory failure as indicated by a baseline (pre-inhalation) capillary blood gas pCO<sub>2</sub> > 8kPa
4. Any clinical suspicion of a condition associated with acutely raised intracranial pressure
5. Currently involved in any other clinical trial of an investigative medical product

**Date of first enrolment**

01/06/2012

**Date of final enrolment**

19/01/2014

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

University of Newcastle

Newcastle Upon Tyne

United Kingdom

NE2 4AA

**Sponsor information****Organisation**

Newcastle Hospitals Foundation NHS Trust (UK)

**Sponsor details**

Wolfson Unit of Clinical Pharmacology

Institute of Cellular Medicine

High Heaton

Newcastle upon Tyne

England

United Kingdom

NE7 7DN

+44 (0)191 233 6161

abc@email.com

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.newcastle-hospitals.org.uk/>

**ROR**

<https://ror.org/05p40t847>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Epilepsy Research UK

**Alternative Name(s)**

ERUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No

