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

Submission date
17/05/2012

Recruitment status
No longer recruiting

Registration date
17/05/2012

Overall study status
Completed

Last Edited
12/12/2017

Condition category
Nervous System Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 pCO2 > 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?
HRA research summary			28/06/2023	No	No