ISRCTN71463496 https://doi.org/10.1186/ISRCTN71463496

Continuous monitoring of body electric signals in Paediatric Intensive Care

Submission date
04/08/2015

Recruitment status
No longer recruiting

Registration date
14/08/2015

Overall study status
Completed

Last Edited
15/12/2016

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In the UK, more than 1.5 million children are admitted to hospital every year, 4,500 of which will require treatment in intensive care. Serious illness can have a big impact on the digestive system and the workload of the muscles involved in breathing (respiratory muscles). Scanning techniques designed to detect electrical activity in the muscles below the skin, such as surface electrogastrography (sEGG) and surface electromyography (sEMG), can help to provide healthcare professionals with more useful information about how these bodily functions are performing than routine testing, which can improve patient care.
These techniques have only been used for short periods of time in the past, however recent improvements in technology mean that they could potentially be used for longer.
This study aims to find out whether these techniques can be used for continuous monitoring of children in paediatric intensive care to provide ongoing information about the digestive system and respiratory muscles.

Who can participate?
Children in intensive care who are able to breathe unaided

What does the study involve?
Eight surface electrode sensors are applied to the bodies of participants. These electrodes are then attached to a special amplifier which in turn is connected to a laptop, which will convert the raw signals into data which can be analyzed.

What are the possible benefits and risks of participating?
There will be no direct benefits or risks to patients participating in this study.

Where is the study run from?
Brimingham Children's Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2014 to December 2015

Who is funding the study?
1. Birmingham Children's Hospital (UK)
2. Inbiolab BV (UK)

Who is the main contact?
Dr Balazs Fule
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number
157604

ClinicalTrials.gov number

Secondary identifying numbers
IRAS project ID 157604

Study information

Scientific Title
Feasibility of continuous surface electro-gastrography (sEGG) and surface electro-myography (sEMG) monitoring in Paediatric Intensive Care

Acronym
ExG

Study objectives
This study is a pilot to establish that we can collect continuous sEGG and sEMG data in the settings of paediatric intensive care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee West Midlands, 01/12/2014, ref: 14/WM/1221

Study design
Observational single-center feasibility medical device study within CE marked intended use

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contatct details below to request a Patient Information Sheet

Health condition(s) or problem(s) studied
Testing continuous surface electro-gastrography (sEGG) and surface electro-myography (sEMG)

Interventions
Acquisuition of surface biopotentials (such as ECG, electromyography and electrogastrography signals) from a set of (8) surface electrodes over a period of 48 hours.

Intervention Type
Device

Primary outcome measure
Feasibility of continuously monitoring ECG, EGG and EMG signals at the same time. Measurements taken at baseline and then at every hour of data collection.

Secondary outcome measures
To identify potential noises that may distort data quality. The presence of electric signals will be decided by expert opinion to provide data quality and quantity measures.

Overall study start date
01/02/2014

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Paediatric ICU patients with spontaneous breathing activity
2. Age between term and 16 years

Participant type(s)
Patient

Age group
Child

Upper age limit
16 Years

Sex
Both

Target number of participants
5

Key exclusion criteria
1. Preterm infants
2. Muscle relaxant infusion at enrollment
3. Open abdomen after abdominal surgery
4. Open skin after sternotomy
5. Burns affecting the torso
6. Skin conditions (limiting use of ECG sensors)

Date of first enrolment
23/06/2015

Date of final enrolment
01/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Children's Hospital
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Sponsor information

Organisation
Birmingham Children's Hospital R&D Department

Sponsor details
Birmingham Children's Hospital
Steelhouse Lane
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England
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B4 6NH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/017k80q27

Funder(s)

Funder type

Funder Name
Birmingham Children's Hospital

Funder Name
Inbiolab BV

Results and Publications

Publication and dissemination plan
As this is a small feasibility study, we are not planning to publish the results in a Journal. We will assess the results (quantity and quality of recorded signals) within our team and may present them on scientific conferences during 2016-2017. You may read the results on the hospital website (www.bch.nhs.uk) or you can e-mail us on PICU.team@bch.nhs.uk.

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