

Continuous monitoring of body electric signals in Paediatric Intensive Care

Submission date 04/08/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/08/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 15/12/2016	Condition category Other	☐ 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?

Birmingham 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

Integrated Research Application System (IRAS)

157604

Protocol serial number

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

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Testing continuous surface electro-gastrography (sEGG) and surface electro-myography (sEMG)

Interventions

Acquisition 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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

16 years

Sex

All

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**

United Kingdom

England

Study participating centre

Birmingham Children's Hospital

Steelhouse Lane

Birmingham

United Kingdom

B4 6NH

Sponsor information**Organisation**

Birmingham Children's Hospital R&D Department

ROR

<https://ror.org/017k80q27>

Funder(s)

Funder type

Funder Name

Birmingham Children's Hospital

Funder Name

Inbiolab BV

Results and Publications

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