

# Continuous monitoring of body electric signals in Paediatric Intensive Care

<b>Submission date</b> 04/08/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/08/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/12/2016	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
balazs.fule@bch.nhs.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Balazs Fule

### Contact details

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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 contact 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**

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 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  
Birmingham  
England  
United Kingdom  
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](http://www.bch.nhs.uk)) or you can e-mail us on [PICU.team@bch.nhs.uk](mailto: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?
<a href="#">HRA research summary</a>			28/06/2023	No	No