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Real-time functional brain imaging using Electrical Impedance Tomography of Evoked Responses

Submission date 11/11/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/11/2009	**Overall study status** Completed	
Last Edited 27/04/2016	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
077724; NRES:07/H1003/H145/CMFT:9644

Study information

Scientific Title
Real-time functional brain imaging using Electrical Impedance Tomography of Evoked Responses: two stage volunteer safety and patient randomised crossover trial

Acronym
fEITER

Study objectives
Functional brain imaging using positron emission tomography has shown that general anaesthesia reduces brain function in a dose-related manner. It is hypothesised that fEITER will derive similar images of human brain function arising from the normal changes in synaptic impedance that occur during cerebral processing of sensory information, but much faster than existing scanning methods and with a suitcase-sized device. We expect fEITER to visualise the reduction in cerebral sensory processing during anaesthesia, and this study will allow the preparation of a dose-response curve indicating the level of anaesthesia with fEITER. Deep surgical anaesthesia has a maximal effect on reducing brain metabolism, so such measurement will permit calibration of the 100% level for sensitivity of fEITER. The null hypothesis is that fEITER will visualise no effect of anaesthesia on brain function.

As of 05/10/2010 the initial end date of this trial has been extended by the funders, the Wellcome Trust. The initial end date at time of registration was 30/09/2010. Stage 1 healthy volunteers is completed (n = 20) and stage 2 patients is recruiting with n = 4 to date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Manchester Research Ethics Committee approved on the 30th January 2008 (ref: 07 /H1003/H145). Confirmation of continued favourable opinion was given on 11th August 2009.

Study design
Two stages:
1. Volunteer safety trial
2. Patient randomised blinded crossover trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Brain function during anaesthesia

Interventions
For both stages 1 and 2, 32 electroencephalogram (EEG) electrodes will be affixed to the scalp at the beginning of the trial (10 minutes). For stage 1 (healthy volunteers), a one-hour trial of fEITER will proceed, comprising sequential one-minute presentations of auditory (click and tone) and visual (flash) sensory stimuli presented in a random sequence during fEITER tomograpic measurements of brain function in response to the sensory stimuli. For stage 2 (anaesthetised patients), an awake tolerance test of two, one-minute presentations of visual and auditory

stimuli will be tested with fEITER (control) and then repeated, sequential one-minute tests of fEITER will be conducted during anaesthesia and surgery. The randomisation and crossover will be in the depth of anaesthesia used (concentration of anaesthetic agent) within normal clinical ranges. Depth of anaesthesia will be assessed before and after each one-minute fEITER test using a commercial depth of anaesthesia monitor (Bispectral Index). The total duration for stage 2 will be the length of surgery, which is variable.

Please note that as of 26/05/10 the end date of this trial has been extended from 30/06/10 to 30 /09/10

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Production of functional brain images that discriminate between different depths of anaesthesia and awake subjects, assessed continuously during the fEITER trial using 1-minute epochs of cerebral conductance data obtained every 10 ms, and determined by off-line analysis, including 3D functional brain image reconstruction, after the trial.

Key secondary outcome(s))
No secondary outcome measures

Completion date
30/04/2011

Eligibility

Key inclusion criteria
Stage 1:
1. Healthy volunteers
2. Aged 18 to 80 years, gender: female, trans or male

Stage 2:
1. American Society of Anaesthesiologists (ASA) grade I - II
2. Adult patients aged 18 to 80 years, gender: female, trans or male
3. Scheduled for elective surgery under routine general anaesthesia

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Key exclusion criteria
Stages 1 and 2:
History of epilepsy or neurological impairment

Date of first enrolment
16/11/2009

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Electrical & Electronic Engineering
Manchester
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Sponsor information

Organisation
University of Manchester (UK)

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Charity

Funder Name

Wellcome Trust (UK) - University Translation Award (grant ref: 077724)

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?
Results article	results:	01/06/2011		Yes	No