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A spectral analysis of human brain tissue

Submission date 30/06/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/06/2010	**Overall study status** Completed	
Last Edited 04/10/2017	**Condition category** Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7568

Study information

Scientific Title
A spectral analysis of human brain tissue: a single-centre non-randomised intra-operative imaging trial

Study objectives
When performing surgery it is essential to identify normal and abnormal brain to guide where surgery should be performed. Computed tomography (CT) and magnetic resonance imaging (MRI) guided surgery is expensive and can have its limitations. It has been hypothesised however that the light reflected from the human brain is subtly different between normal and abnormal tissue. This is so subtle that as to not be apparent to the naked eye but may be detectable if the light is split into its individual wavelengths' and analysed by a very sensitive camera. If these differences are detectable then this could form the basis of new ways of making surgery safer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and Southwest Hampshire Research Ethics Committee, 22/02/2007, ref: 06/Q1704/139

Study design
Single-centre non-randomised interventional diagnosis and screening trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Neurological; Subtopic: Neurological (all Subtopics); Disease: Nervous system disorders

Interventions
Any patient undergoing craniotomy in the Wessex Neurological Centre will be considered. Appropriate consent will be obtained from the patient. At surgery up to five image acquisitions will be made. Each image acquisition will last up to 2 minutes and will consist of the full spectral analysis at fixed points followed by field images of fixed wavelengths. A photographic image and copy of the MRI scan will also be take to correlate spectral traces with conventional means of identifying normal and abnormal tissue. These images will then be analysed post-operatively and not be used to guide surgery or influence patient management.

The main arm of the trial will attempt to differentiate normal and abnormal brain. This will be done in patients under general anaesthetic as described above. The second arm will try to assess if the reflectance of the brain changes with function. This will be a smaller cohort of patients, as they will be undergoing awake craniotomy. During surgery images will be obtained before and during basic tasks performed for standard cortical mapping such as speech and hand squeezing to assess for any changes.

Data will be collected on a laptop computer before applying noise reduction and normalising data. Graphical representations of spectroscopic traces will be assessed for unusual signatures and differences between pathological and non-pathological tissue and between functioning and non-functioning cortex assess using a student's t-test. Data will be stored anonymously on a networked university computer for up to ten years.

The duration on the intervention is 10 minutes added to the usual surgery time. This group of patients are not followed up for trial purposes. There are no treatment arms here: images are acquired for research purposes without any management implications for the individual patients.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Difference in reflection between normal brain tissue and abnormal brain tissue, acquired at the time of image acquisition

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/2007

Completion date
01/06/2012

Eligibility

Key inclusion criteria
Any patient (over 16 years) undergoing craniotomy in Wessex Neurological Centre

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned sample size: 200

Key exclusion criteria
1. Aged less than 16 years
2. Pregnancy
3. Prisoners
4. Patients incapable of consent

Date of first enrolment
01/06/2007

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Aldermoor Close
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SO16 5ST

Sponsor type
University/education

Website
http://www.soton.ac.uk/

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Central Commissioning Facility (CCF): New and Emerging Applications of Technology (NEAT) Programme

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