

A spectral analysis of human brain tissue

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

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 taken 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

Southampton

England

United Kingdom

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