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Pilot randomised controlled trial of deep brain stimulation in Tourette syndrome

Submission date	Recruitment status	[X] Prospectively registered
02/07/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/07/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/06/2016	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01647269

Protocol serial number
V 1.0

Study information

Scientific Title
Pilot randomised controlled trial of deep brain stimulation in Tourette syndrome

Study objectives
Current hypothesis as of 05/12/2007:
That bilateral deep brain stimulation applied to the globus pallidus internum will improve symptoms of Tourette syndrome, as measured by the Yale Global Tic Severity scale, when compared to sham stimulation.

Previous hypothesis:
That deep brain stimulation applied to the globus pallidus internum bilaterally will reduce tic scores significantly over one year compared to sham stimulation in Tourette syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval applied for via:
1. COREC on 06/06/2007
2. NRES in December 2007

Primary study design
Interventional

Study design
Randomised placebo-controlled crossover study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tourette syndrome

Interventions
Current interventions as of 05/12/2007:
Group 1:
Group 1 will have deep brain stimulation electrodes placed in the globus palludus internum. After 6 weeks, the electrodes will be switched on and adjusted maximally. After 3 months, electrodes will be switched off and the patient followed up after a further 3 months.

Group 2:
Group 2 will have deep brain stimulation electrodes placed in the globus pallidus internum. After 6 weeks, the participant will have a "sham" switching on of electrodes. After 3 months, the electrodes will be switched on and adjusted maximally. The patient will be followed up and assessed after a further 3 months.

Previous interventions:
Intervention group:
Intervention group will have deep brain stimulation electrodes placed in globus pallidus externum. After 6 weeks, the electrodes will be switched on and further adjusted at 12 and 18 weeks. Follow-up assessments will then happen at 6 months, 9 months and 12 months.

Control group:
Control group will also have severe Tourette syndrome. They will also have electrodes implanted in the same way as the patients. After 6 weeks they will have a "sham switch on" proceedure. Follow-ups will be done in the same way as the intervention group.

After one year of treatment, the code will be broken and data analysed. Participants in the intervention and control group will then be invited to participate in a further year of open-label extension study with all stimulators switched on. Data will then be gathered at 18 and 24 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Yale Global Tic severity scale.

Key secondary outcome(s)
1. Yale-Brown Obsessive Compulsive Scale
2. Hospital Anxiety and Depression Scale
3. Total Subjective Quality Of Life (TS-QOL)

Completion date
01/04/2010

Eligibility

Key inclusion criteria
Adults with medically intractable Tourette syndrome for whom surgery and post-operative care is not contraindicated.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Tics for other neurological reasons
2. High risk for surgery or post-op care

Date of first enrolment
01/04/2008

Date of final enrolment

01/04/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Elizabeth Psychiatric Hospital
Birmingham
United Kingdom
B15 2QZ

Sponsor information

Organisation
University Hospital Birmingham NHS Foundation Trust (UK)

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Charity

Funder Name
Tourette Syndrome Association (UK) - applied for funding

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	01/06/2015		Yes	No