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Electrical brain activity patterns in children with Tourette syndrome and ADHD

Submission date	Recruitment status	[ ] Prospectively registered
25/07/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/07/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/08/2016	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Tourette syndrome (TS) is a disorder that begins in childhood. Children with TS have difficulty controlling involuntary movements and sounds (tics). The cause of TS is unknown and treatments used to control tics are often not effective. Frequently, children with TS also have symptoms of attention-deficit/hyperactivity disorder (ADHD). These symptoms include poor attention, hyperactivity (being unable to keep still for long) and impulsivity (being unable to wait). Children with symptoms of TS and ADHD are referred to as having comorbid TS+ADHD. These children have more serious problems at school and home and are more difficult to treat successfully than children without comorbid ADHD. This study aims to improve understanding of the causes of these conditions, particularly the reasons for and impact of having ADHD in addition to TS.

We will examine the patterns of brain activity associated with learning (the process of acquiring new behaviours) and cognitive control (the ability to voluntarily control behaviour) in children with TS, ADHD and TS+ADHD and unaffected children. Learning and cognitive control are controlled by the same brain networks that are thought to be different in children with TS and ADHD. Studying the basis of these cognitive functions in TS and TS+ADHD should therefore reveal important insights into the causes of these conditions. Participants will perform a computerised task designed to tap learning and cognitive control while their brain activity is recorded with a technique called electroencephalography (EEG). We will compare differences in brain activity patterns across participant groups to establish differences between TS, ADHD and unaffected children in these cognitive functions, and to examine how such differences interact in TS+ADHD.

Who can participate?

Young people with a diagnosis of TS, ADHD or TS+ADHD can take part if they are aged between 9-17 years and do not have an autistic spectrum disorder (ASD) or severe learning difficulty. Young people aged 9-17 years can take part in the typically developing control group if they do not have a diagnosis of any developmental condition.

What does the study involve?

The study consists of two parts. Part 1 consists of an interview session with each participants parent/carer to assess the presence or absence of developmental problems. Part 2 of the study

is an EEG recording session in which the participant has their brain activity measured using EEG while they perform two computer tasks. EEG is a non-invasive and painless technique in which a cap is placed on the participants head and electrodes are placed in holes on the cap to record the brain activity at the scalp.

What are the possible risks and benefits of participating?
The possible benefits of participating are to gain first-hand experience of taking part in a research study, and to contribute to research which we hope will help improve understanding of the causes of two developmental disorders. We anticipate no risks resulting from taking part.

Where is the study run from?
University of Nottingham (UK)

When is the study starting and ending?
The study began in March 2012 and we hope to finish testing participants by February 2013. Analysis should be complete by September 2013.

Who is funding the study?
University of Nottingham and Shire Pharmaceuticals plc.

Who is the main contact?
Miss Elizabeth Shephard
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Contact information

Type(s)
Scientific

Contact name
Miss Elizabeth Shephard

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

12083

Study information

Scientific Title
Electrophysiology of LEarning and Cognitive control in children with Tourette syndrome with and without Attention-deficit/hyperactivity disorder

Acronym
ELECTA

Study objectives
Tourette syndrome (TS) is a disorder that begins in childhood. Children with TS have difficulty controlling involuntary movements and sounds (tics). The cause of TS is unknown and treatments used to control tics are often ineffective. Frequently, children with TS also have symptoms of attention-deficit/hyperactivity disorder (ADHD). These symptoms include poor attention, hyperactivity (being unable to keep still for long) and impulsivity (being unable to wait). Children with symptoms of TS and ADHD are referred to as having comorbid TS+ADHD. These children have more serious problems at school and home and are more difficult to treat successfully than children without comorbid ADHD. This study aims to improve understanding of the causes of these conditions, particularly the reasons for and impact of having ADHD in addition to TS. We will examine patterns of electrophysiological brain activity associated with associative learning (learning behaviours by strengthening associations between behaviours and responses) and cognitive control (voluntary control of behaviour) in children with TS, ADHD, TS+ADHD, and unaffected controls. Associative learning and cognitive control are controlled by the same brain networks that are thought to be atypical in TS and ADHD. Studying the neural basis of these cognitive functions in TS and TS+ADHD should therefore reveal important insights into the causes of these conditions. Participants will perform a computerised task designed to tap associative learning and cognitive control while their electrophysiological brain activity is recorded with electroencephalography (EEG). Behavioural and electrophysiological measures of associative learning and cognitive control will be compared across participant groups to establish differences between TS, ADHD and controls in these cognitive functions, and to examine how such differences interact in TS+ADHD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicester NHS Research Ethics Committee - Nottinghamshire Healthcare NHS Trust, 13/03/2012, ref: 11/EM/0339

Study design
Non-randomised interventional single-centre trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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
Attention deficit hyperactivity conduct disorder

Interventions
Electrophysiological testing, Each participant will complete an electrophysiological testing session in which they will perform a computerised learning and cognitive control task while their electrophysiological brain activity is recorded by electrodes placed on the scalp (technique known as electroencephalography or EEG)
Follow Up Length: 12 month(s)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Performance variables and electrophysiological correlates of learning and cognitive control. Collected once from each participant in the next 12 months

Secondary outcome measures
No secondary outcome measures

Overall study start date
14/03/2012

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Diagnosis of TS without diagnosis of ADHD (children and adolescents with TS without ADHD)
2. Diagnosis of ADHD without diagnosis of TS (children and adolescents with ADHD without TS)
3. Diagnosis of TS with ADHD symptoms (children adolescents with TS with ADHD)
4. Male & Female

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
UK Sample Size: 90

Key exclusion criteria
1. Known neurological problem that would likely influence brain function e.g. epilepsy
2. Diagnosed learning difficulties or IQ score less than 70 points as this may prevent participants being able to perform the task
3. Diagnosis of any psychiatric condit

Date of first enrolment
14/03/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queens Medical Centre
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Division of Epidemiology and Public Health
Nottingham
England
United Kingdom
NG7 2RD

Sponsor type
University/education

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

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Industry

Funder Name
Shire

Alternative Name(s)
Shire plc

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

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