European Multicentre Tics in Children Study

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To explore the complex interaction between environment, autoimmunity and genetics in relation to the onset and clinical course of tic disorders and associated obsessive-compulsive symptoms and to translate these findings into clinical applications....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational invasive

Summary

ID

NL-OMON40209

Source
ToetsingOnline

Brief title
EMTICS

Condition

- Movement disorders (incl parkinsonism)

Synonym
Tourette's disorder; Tourette syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: cortisol, Group A Streptococcus, Tics, Tourette syndrome

Outcome measures

Primary outcome

The main study outcome is onset of tics (ONSET study) and tic exacerbations (COURSE study), as assessed by the Yale Global tic severity scale (YGTSS) plus Premonitory Urge for Tics Scale (PUTS).

Secondary outcome

Other main parameters are the presence of obsessive-compulsive symptoms as assessed by the Children*s Yale Brown Obsessive-Compulsive Scale (CY-BOCS) and the presence of GAS in throat swabs.

Study description

Background summary

The aetiology of tic disorders and associated obsessive-compulsive and behavioural symptoms is poorly understood. It has been postulated that genetic and environmental factors active upon regulatory systems (e.g. immune and endocrine systems) might interact in creating a neurobiological vulnerability to the development of tics and associated behaviours. The largest body of evidence from clinical research has been gathered in support of a role of exposure to psychosocial stress, of pregnancy and delivery adversities and of infections from GAS (Murphy, Kurlan, and Leckman, 2010). The human pathogen GAS is a major cause of common pharyngitis, but also of significant post-streptococcal non-suppurative autoimmune multi-organ sequelae associated with the existence of host autoantibodies against GAS antigens (also known as the Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections [PANDAS]-hypothesis). However, the mechanisms leading to such vulnerability are still largely undefined.

Study objective

To explore the complex interaction between environment, autoimmunity and

genetics in relation to the onset and clinical course of tic disorders and associated obsessive-compulsive symptoms and to translate these findings into clinical applications. We aim to identify the role of exposure to specific environmental factors, including new exposure to specific molecular GAS types and/or subtypes in the form of pharyngeal carriage or infection and psychosocial stress on the onset and course of tics, as well as to identify the human gene pathways that are activated upon symptom exacerbations, by implementing longitudinal genome wide gene expression studies.

Study design

This is a longitudinal observational European multicenter study consisting of an ONSET and COURSE study part. European sites together will recruit 375 children in the ONSET and 700 children in the COURSE study. The UMCG/de Bascule will recruit respectively 25 and 45 children.

Study burden and risks

The burden will be completion of parent-questionnaires (maximal 11 x 20 minutes = 220 min), child-questionnaires (maximal 10 x 10 minutes = 100 min), telephone interviews with the parent (maximal 9 x 20 minutes = 180 min), completion of a weekly home diary by the parent (maximal 126 x 5 minutes = 630 min), and clinical evaluations (maximal 11 x 60 minutes = 660 min), blood draws by venipuncture (maximal 10 times), throat swabs (maximal 4 times) and collection of hair strands (maximal 10 times) in the child.
Risks and physical or physiological discomfort will be negligible.
Participation in the study will be of no benefit to individual patients, however, the study will benefit the population at large, possibly helping the participants* younger siblings and future families.
This research protocol includes the participation of minors. Tic disorders have a childhood onset. Tics often lessen in intensity and frequency or may even disappear in adulthood. To do a proper study it is unavoidable to also involve minors.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

ONSET Study:
1. First degree relative of person with TS or another chronic tic disorder according to DSM IV-TR criteria (American Psychiatric Association)
2. Aged 3-10 years, male or female
COURSE STUDY:
1. Having TS or another chronic tic disorder according to DSM IV-TR criteria (American Psychiatric Association)
2. Age 3-16 years, male or female;Parents and patients have provided written informed consent and assent as appropriate according to ethical regulation

Exclusion criteria

ONSET:
1. Presence of tics
2. Presence of OCD
3. Serious medical illness
4. Child treated with antibiotics in the past 1 month.
5. Children and/or parents are unable to understand and comply with protocol.
COURSE:
1. Serious medical illness
2. Child treated with antibiotics in the past 1 month.

3. Children and/or parents are unable to understand and comply with protocol

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2014
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	08-08-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	24-07-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL44008.042.13