

# Collaborative Genomic Studies of Tourette\*s Disorder

Published: 20-09-2011

Last updated: 29-04-2024

The purpose of the study is to identify genes and genetic mechanisms that contribute to TD, chronic tics, and related clinical disorders including OCD and ADHD in individuals with these clinical phenotypes and their relatives.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Developmental disorders NEC
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON55561

### Source

ToetsingOnline

### Brief title

TIC Genetics

### Condition

- Developmental disorders NEC

### Synonym

Tourette's disorder; Tourettes

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Accare

**Source(s) of monetary or material Support:** National Institute of Mental Health van de VS

## Intervention

**Keyword:** ADHD, DNA biobank, genetics, Tourette's disorder

## Outcome measures

### Primary outcome

Presence of TD or other tic disorders (including chronic motor or vocal tic disorder, transient tic disorder, and tic disorder not otherwise specified).

### Secondary outcome

Symptoms of OCD (including subclinical OCD and Obsessive-Compulsive personality disorder); symptoms of ADHD and trichotillomania.

## Study description

### Background summary

Tourette's Disorder (TD) is a developmental neuropsychiatric syndrome characterized by persistent vocal and motor tics. While initially considered rare, the prevalence is now estimated to be 0.3-1%. Both as a result of potentially disabling symptoms and high rates of psychiatric co-morbidity, particularly with obsessive-compulsive disorder (OCD) and attention-deficit/hyperactivity disorder (ADHD), TD represents a significant public health concern. This protocol is part of an international collaborative group, entitled \*Tourette International Collaborative Genetics (TIC Genetics)\*. The DNA, cell lines, and clinical information will be stored at Rutgers University as part of the National Institutes of Mental Health (NIMH) Center for Collaborative Genetic Studies on Mental Disorders as an international resource.

### Study objective

The purpose of the study is to identify genes and genetic mechanisms that contribute to TD, chronic tics, and related clinical disorders including OCD and ADHD in individuals with these clinical phenotypes and their relatives.

### Study design

This is an international cross-sectional genetic biobanking multicenter study

in which seven US sites, fourteen European sites (including three recruiting sites from the Netherlands: UMCG, Yulius, de Bascule), and six South-Korean sites will perform a diagnostic assessment, followed by a single blood draw, aimed in 6300 individuals over a study period from 2011 to 2024, all being either parent-child trio\*s or affected or unaffected members of pedigrees with three or more affected members with TD or chronic tics. European sites together will recruit at least 25 multiply affected extended families plus parent-child trio\*s with a maximum of 2100 subjects over the study period 2011-2024.

### **Study burden and risks**

The burden will be completion of a questionnaire (60 minutes), a single clinical evaluation (60 minutes), and a blood draw (15 minutes) through venipuncture. Risks will be negligible. Subjects will not receive any direct benefits from participation in the research. This research protocol includes the participation of minors. Tic disorders have a childhood onset, with tics usually starting around the age of 6.

## **Contacts**

### **Public**

Accare

Hanzeplein 1, XA-10

Groningen 9713 GZ

NL

### **Scientific**

Accare

Hanzeplein 1, XA-10

Groningen 9713 GZ

NL

## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

### Inclusion criteria

Either parent-child trios (i.e. affected person with Tourette's disorder plus his/her biological parents) or extended pedigrees, with a primary proband with Tourette's disorder and at least two relatives (up to the fourth degree) who are affected with Tourette's Disorder or chronic motor tic disorder.

### Exclusion criteria

No informed consent or resistance of minors against blood sampling

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 02-02-2012

Enrollment: 1002

Type: Actual

## Ethics review

Approved WMO

Date: 20-09-2011

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 05-12-2012

Application type: Amendment

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)

Not approved

Date: 04-03-2016

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 25-10-2017

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 13-04-2022

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	NL37812.042.11