Multicenter Aggression subTyping Research in Conduct Syndromes: An exploratory study

Published: 30-04-2015
Last updated: 21-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Personality disorders and disturbances in behaviour
Study type	Observational invasive

Summary

ID

NL-OMON41946

Source
ToetsingOnline

Brief title
MATRICS

Condition

- Personality disorders and disturbances in behaviour

Synonym
conduct disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: European Community□s Seventh Framework Programme (FP7/2007-2013);n° 602805 en n° 603016

Intervention

Keyword: aggression, brain, conduct disorder, genetics

Outcome measures

Primary outcome

Scores on questionnaires about CU traits, aggression and conduct problems are the independent variables in this study. The main outcome measures are (1) performance on tasks of emotion recognition, impulsivity and memory (2) volume size of prefrontal and limbic brain regions, white matter integrity, functional network connectivity, and brain activation during a face matching task, passive avoidance task and stop signal task (3) anterior cingulate and striatal glutamate concentration and (4) aggression related genotypes as well as hormone levels.

Secondary outcome

Additional measures include hair cells to be reprogrammed into human induced pluripotent stem cells (hiPSCs) and optionally, a stool sample to investigate the human microbiome (bacteriome). The stool samples will be collected at a later time from participants that give consent for this extra part of the study.

Study description

Background summary

Children and adolescents with oppositional defiant disorder (ODD) or conduct disorder (CD) show a repetitive and persistent pattern of aggressive behaviour. One can distinguish between different forms of aggression, such as uncontrolled, emotional, *impulsive aggression* and planned, goal-directed

instrumental aggression. Another distinction is based on the presence of callous-unemotional (CU) traits, defined as a lack of prosocial emotions. These subtypes may be mediated by unique underlying mechanisms. More knowledge is needed about the behavioural, cognitive, neural and (neuro)biological as well as genetic bases of aggression in childhood- and adolescent-onset CD and/or ODD.

Study objective

The main objectives of this study are to (I) investigate characteristics of children and adolescents with CD and/or ODD in comparison with typically developing (TD) controls and (II) examine subtypes of aggression on the behavioural, cognitive, neural, (neuro)biological and genetic level.

Study design

This is a multicentre cross-sectional study in which nine European research sites are involved. In the Netherlands, data will be collected at Radboud University Medical Centre and University Medical Centre Groningen. Children/adolescents will fill in online questionnaires and visit the centre for a test day with a parent/guardian. A test day consists of a diagnostic interview, an MRI session (structural MRI, resting state scan, Diffusion Tensor Imaging and functional MRI with three tasks), an MRS session, a behavioural-cognitive session, ECG measurement, venipuncture and collection of a hair sample and saliva samples. The parent/guardian is interviewed as well and will be asked to fill in questionnaires about their child.

Study burden and risks

The proposed study includes an invasive measure, the collection of a blood sample (30 ml.), which is necessary for DNA, RNA and proteomics isolation. Participants will also undergo MRI and MRS scanning. Scanning time per session is limited to 60 minutes to minimize burden. The degree of anxiety and pleasure will be monitored before and during the MRI session. If children show resistance, the procedure will be stopped immediately. With informed consent, hair samples will be collected and reprogrammed into hiPSCs. Collecting hair cells is preferable over alternative methods such as collecting skin cells, since it greatly reduces the burden on children and adolescents. Participants will be between 8 to 18 years old, since we investigate CD and/or ODD which has an onset in childhood or adolescence. Our objectives can only be achieved by including minors, since the aggressive and antisocial behaviours that we are interested in develop during this age range. There are no special risks associated with our research and we have ample experience with these types of procedures (see Compuls, NL42004.091.12; NeuroIMAGE, NL23894.091.08; NeuroIMAGE-II, NL41950.091.12; the Accelerated Longitudinal Study in Autism,

NL45500.091.13).

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Kapittelweg 29
Nijmegen 6525 EN
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Kapittelweg 29
Nijmegen 6525 EN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

age 8 - 18
IQ > 80;for the patient group:
diagnosis of ODD/CD
aggression in the clinical range

Exclusion criteria

IQ < 80
diagnosis of psychosis, bipolar disorder, depression or anxiety
contra-indications for MRI, e.g., metal parts in the body

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-04-2016
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	30-04-2015
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	19-05-2016
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den

Haag)

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	NL49997.091.14