Excitatory/Inhibitory imbalance in autism spectrum disorder

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To define a link between excitatory/inhibitory (glutamate/GABA) neurotransmission and neural functioning across different brain regions (regional specificity) and to establish the relation between this link and ASD symptomatology (tapping into...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Developmental disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON49625

Source
ToetsingOnline

Brief title
Equilibrium

Condition

- Developmental disorders NEC

Synonym
ASD, autism

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO (Veni)

Intervention

Keyword: autism spectrum disorder, GABA, glutamate, imbalance

Outcome measures

Primary outcome

ASD symptoms (continuous measures of repetitive behavior problems and abnormal sensory processing as measured with the Repetitive Behaviour Scale and the Short Sensory Profile) and the degree to which these symptoms are associated with MRI-based functional and neurochemical measures in the anterior cingulate cortex (ACC) and visual cortex (V1) will be investigated.

Secondary outcome

N/A

Study description

Background summary

Autism Spectrum Disorder (ASD) is a very heterogenous group of disorders characterized by qualitative impairments in social interactions and communication, and a range of repetitive/ restricted behaviours and interests and abnormal sensory processing. Clinical diagnosis is still based solely on behavioural classification. No biomarkers have been established to aid in diagnosing or stratifying ASD. In this study entitled *Excitatory/Inhibitory imbalance in autism spectrum disorder* (Equilibirium) we will apply an innovative MRI technique to investigate an important hypothesis of ASD that assumes an imbalance between excitatory and inhibitory neurotransmission to be underlying ASD symptomatology.

Study objective

To define a link between excitatory/inhibitory (glutamate/GABA) neurotransmission and neural functioning across different brain regions (regional specificity) and to establish the relation between this link and ASD symptomatology (tapping into clinical heterogeneity).

Study design

ASD participants and controls will be selected from an existing ASD study (LEAP3-protocol, NL72033.091.19) and will be invited for an additional MRI-protocol at 7 Tesla and/or will be recruited from a volunteer database of the department of psychiatry at the Radboudumc, Nijmegen, the Netherlands.

Study burden and risks

All participants will be adults older than 20 years. The risk of participating in this study is negligible. MRI, also at 7 Tesla, when conducted following standard protocols and screening, has no known adverse health effects. We anticipate novel findings using this innovative MRI procedure in which we measure neural functioning and chemistry simultaneously, which is only attainable using 7 Tesla. Incidental neurological findings may have consequences for the participants. Patients will not benefit directly from participating in the study, but they will contribute to knowledge that may lead to improved treatments in the long term.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 years or older
Dutch speaking
Normal or corrected-to-normal vision
Willingness and ability to understand nature and content of the study
IQ > 70
An established clinical diagnosis of autism spectrum disorder according to the DSM-5 criteria (patient group only)

Exclusion criteria

History of brain surgery or epilepsy
History of neurological treatment
Any acute or chronic neurological disorders.
Pregnancy
Claustrophobia
MRI incompatibility (metal parts in upper body, implants, medical devices or medicinal plasters)
There is presence of a diagnosis of psychosis or bipolar disorder (patient group)
There is presence of any DSM-5 axis I or axis II psychiatric disorders (control group)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO Date:	23-06-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL72899.091.20