# The microbiome in Asperger syndrome: A pilot study

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Psychiatric disorders NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON49403

**Source**
ToetsingOnline

**Brief title**
MBA

### Condition

- Psychiatric disorders NEC

**Synonym**
Asperger syndrome; autisme with normal cognition

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** aetiology, Asperger syndrome, autism, microbiome

## Outcome measures

### Primary outcome

Differences in results of the various gut microbiome constituents by HITChip flora mapping, between each Asperger individual and his/her sib, and between the group of Asperger individuals and the group of sibs

### Secondary outcome

a. Determining whether a difference in microbiome, if present, correlates with the diet

b. Determining whether there is a correlation between bacterial DNA in platelets and bacterial fecal composition

# Study description

### Background summary

Autism is a well-known behavioural characteristic which has a high prevalence in individuals with intellectual disability. Autism that goes along with intellectual disability is known to have a very large number of causes, especially chromosome imbalances and changes in Mendelian genes. Asperger syndrome is characterized by autism but with near-typical language development and without intellectual disability. Studies to detect causes of Asperger syndrome have invariably failed to show abnormalities; especially no chromosome anomalies or mutations in Mendelian genes can be detected. This indicates there may be non-genetic causes. We suggest here that one of the causative factors may be a disturbance in the gut microbiome. There is growing evidence of a strong brain-gut axis, and an association between the gut microbiome and behaviour. Several small studies have indicated that individuals with autism plus intellectual disability can have a microbiome that differs from the microbiome in neurotypical individuals. To date, no microbiome studies have been done in individuals with Asperger syndrome however.

The way a gut-brain axis functions is at present unknown. We suggest the *transport* of microbiome information works through thrombocytes, and that there is a local action through a change in the methylation status of brain cells.

### Study objective

The primary objective is determining whether there is a difference in faecal microbiome constitutions in individuals with Asperger syndrome compared to their non-affected sibs. The secondary objectives are whether there is a correlation between microbial DNA in thrombocytes and the microbiome. We will also investigate whether this is influenced by the diet.

### Study design

Pilot case-control study

### Study burden and risks

The burden of registering the normal diet of participants for 2 days represents a negligible burden and also the single harvesting of faeces, performed at home, is no burden. Only the blood sampling is a burden especially in the children aged 12-18years. We have considered performing the study in adults only. However we reasoned that irrespective the results in adults this study needs to be performed in children as well, as it remains uncertain whether results in adults can be translated to the paediatric group and vice versa. As a single blood sampling in the group 12-18years is still a limited burden, and as the study has the potential to offer a significant benefit to the group of children with Asperger as a whole, we considered it acceptable to perform the study in children.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Patients
- diagnosis Asperger syndrome as established by an experienced psychiatrist
- willing and able to donate a faeces sample, register diet and donate a single blood sample
- able to provide informed consent
Controls
- sib of individual with Asperger but without symptoms of Asperger syndrome as established by an experienced psychiatrist
- willing and able to donate a faeces sample, register diet and donate a single blood sample
- able to provide informed consent

## Exclusion criteria

- use of probiotica
- recent antibiotics use (last 3 months)

# Study design

### Design

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|---|---|
| Study type: | Observational invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Basic science

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-10-2018 |
| Enrollment: | 40 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 21-11-2016 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## 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 | NL59303.018.16 |