

# Role of the Gut Vascular Barrier and Microbiota in Autism Spectrum Disorders

NCT07450443

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2, Phase 3
<b>Sponsor</b>	Fondazione I.R.C.C.S. Istituto Neurologico Carlo Besta
<b>Enrollment</b>	90 participants

## Key Eligibility Criteria

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### Inclusion (8)

- Group 1 and 2:
  - Diagnosis of ASD according to DSM-5 diagnostic criteria;
  - Clinical neurological evaluation by child neurologist and neuropsychologist with administration of standardized instruments such as Autism Diagnostic Observation Schedule-2 (ADOS-2) and/or Autism Diagnostic Interview-Revised (ADI-R) to support diagnosis;
  - Assessment of psychomotor or intellectual development (Griffiths Scales, Wechsler Scales, Leiter Scale)
  - Assessment of the following symptoms in the past three months: constipation, diarrhea, abnormal stool consistency, abnormal stool smell, flatulence, abdominal pain, unexplained daytime irritability, and nighttime awakening, and abdominal tenderness. The degree of gastrointestinal disturbances will be quantified before recruitment using an Italian version of the GI Severity Index. A score of at least 2 in a single item of gastrointestinal symptoms (item 1-6) was required for entry into the symptomatic group.
- ... and 3 more (see full listing online)

### Exclusion (7)

- Group 1 and 2
  - Children with syndromic ASD or defined genetic diseases;
  - Subjects with significant health problems requiring surgical treatment or continuous medical treatment;
  - Severe gastrointestinal problems requiring immediate (life-threatening) treatment;
  - Severely underweight/malnourished children;
- ... and 2 more (see full listing online)

## Locations (2 total)

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Fondazione IRCCS Istituto Neurologico Carlo Besta, Milan, MI, Italy  
IRCCS Humanitas Research Hospital (ICH) Laboratory of Microbiota and Mucosal Immunology, Milan, Italy