

# Proteomic Biomarker Tests in Blood Samples from Children with Autism Spectrum Disorder (ASD)

NCT02168868

---

**Status** RECRUITING  
**Sponsor** Benjamin Gesundheit  
**Enrollment** 900 participants

## Key Eligibility Criteria

---

### Inclusion (3)

- Male and female children
- Child aged 2-12 years with diagnosed ASD according to Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV (299.00) or DSM-V (299.00) OR Child aged 2-18 years diagnosed ASD according to DSM-IV (299.00) or DSM-V (299.00) AND scheduled to undergo stem cell transplantation OR Child aged 10-19 months not diagnosed with ASD but with a sibling diagnosed with ASD according to (DSM)-IV (299.00) or DSM-V (299.00) (herein termed "high-risk infants") OR Mothers of recruited high-risk infants OR A typically developing child aged 2-12 years with no signs of ASD or history of ASD in the immediate family
- Informed consent signed by the parent/legal guardian

### Exclusion (6)

- Child and/or mother completed treatment with systemic steroids or immune suppressants less than 4 weeks before the screening visit
- Child and/or mother diagnosed with severe infectious diseases or sepsis over the last 6 months
- Child with ASD treated for a severe convulsive disorder (intractable seizures)
- Child and/or mother with hematological or malignant disorder
- For children in the SCT cohort: No new planned immune-modulating treatment (other than SCT) for at least 6 months before or after planned stem cell transplantation date
- ... and 1 more (see full listing online)

## Locations (1 total)

---

Shaare Zedek Medical Center, Jerusalem, Israel