# A Pilot, Multicentre, Controlled, Open-label Study Evaluating 24 Months of Lithium Carbonate Treatment in Patients With TBR1-related Neurocognitive Disorder

NCT06776848

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| **Status** | RECRUITING |
| **Phase** | Phase 1, Phase 2 |
| **Sponsor** | Centre Hospitalier Universitaire Dijon |
| **Enrollment** | 12 participants |

## Key Eligibility Criteria

### Inclusion (8)

- Written informed consent from the patient, parent or legal representative
- e6 years old at the time of consent
- Proven pathogenic or probably pathogenic TBR1 variant (SNV confirmed by Sanger sequencing or CNV including only TBR1)
- If applicable: Stable concomitant psychoactive medication regimen (dose and schedule) e2 months prior to lithium initiation
- Affected individuals able to take tablet /capsules orally

... and 3 more (see full listing online)

### Exclusion (23)

- Criteria related to associated pathologies leading to particular risks:
- Renal/liver insufficiency (disturbed liver function, abnormal creatinine clearance)
- Unbalanced thyroid or diabetic pathology
- Long QT/Brugada syndrome or familial antecedent of Brugada syndrome, cardiac insufficiency
- Addison disease, dehydration, sodium restriction

... and 18 more (see full listing online)

## Locations (1 total)

CHU Dijon Bourgogne, Dijon, France