

# To Investigate the Efficacy of Treatment With Oral NA-921 (Bionetide) Versus Placebo in Females With Rett Syndrome

NCT06840496

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Status	RECRUITING
Phase	Phase 3
Sponsor	Biomed Industries, Inc.
Enrollment	210 participants

## Key Eligibility Criteria

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### Inclusion (9)

- Female subjects 5 to 20 years of age, inclusive, at Screening
- Body weight  $\geq$  12 kg at Screening
- Can swallow the study medication provided as a liquid solution or can take it by gastrostomy tube
- Has classic/typical Rett syndrome (RTT)
- Has a documented disease-causing mutation in the MECP2 gene

... and 4 more (see full listing online)

### Exclusion (6)

- Has been treated with insulin within 12 weeks of Baseline
- Has current clinically significant cardiovascular, endocrine (such as hypo- or hyperthyroidism, Type 1 diabetes mellitus, or uncontrolled Type 2 diabetes mellitus), renal, hepatic, respiratory or gastrointestinal disease (such as celiac disease or inflammatory bowel disease) or has major surgery planned during the study
- Has a history of, or current, cerebrovascular disease or brain trauma
- Has significant, uncorrected visual or uncorrected hearing impairment
- Has a history of, or current, malignancy

... and 1 more (see full listing online)

## Locations (18 total)

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Biomed Testing Facility # BIO-01-85012, Phoenix, Arizona, United States  
Biomed Testing Facility # BIO-05-92093, La Jolla, California, United States  
Biomed Testing Facility # BIO-04-90095, Los Angeles, California, United States  
... and 15 more locations