

Effect of Large Neutral Amino Acids in Adults With Classical Phenylketonuria

NCT06337864

Status	RECRUITING
Phase	Not Applicable
Sponsor	Rigshospitalet, Denmark
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (6)

- Patients e 18 years of age with Classical PKU molecularly confirmed via the finding of two pathogenic variants in the phenylalanine hydroxylase (PAH) gene and/or historical evidence of Phe concentrations e1200 μ ol/L in the medical history
- Treatment initiation within the first month of life
- Intelligence quotient over 84, based upon the baseline neuropsychological evaluation
- Conventional dietary treatment up to minimum 15 years of age
- Signed informed consent
- ... and 1 more (see full listing online)

Exclusion (8)

- Unable or unwilling to adhere to the requirements of the study
- A female who is pregnant or breastfeeding or planning to get pregnant during the study period
- Concomitant medication that may interfere with the PET analysis, as judged by the investigator
- A serious neuropsychiatric disease that could interfere with the subject's ability to participate in the study at the discretion of the investigator
- Concomitant treatment with BH4 supplementation (sapropterin) or Pegvaliase-pqz (PALYNZIQ)
- ... and 3 more (see full listing online)

Locations (2 total)

Center for Inherited Metabolic Diseases, Copenhagen, Denmark
Copenhagen University Hospital, Rigshospitalet, Copenhagen, Denmark

<https://clinicaltrials.gov/study/NCT06337864>

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