PHOENIX

AMYLYX
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About the PHOENIX Trial

The **PH**ase 3 S**O**dium Ph**EN**ylbutyrate and Taurursod**I**ol (also known as Ursodo**X**icoltaurine) (PHOENIX) trial will evaluate whether an investigational product called PB and TURSO is safe and effective as a treatment for adults living with amyotrophic lateral sclerosis (ALS).

The PHOENIX trial is a randomized, placebo-controlled phase 3 trial with ≤600 participants in the United States and Europe.

Each participant will be in the PHOENIX trial for approximately 1 year.

The PHOENIX trial is designed to be telemedicine friendly, with a total of 6 or fewer in-person visits.

Participants will be randomly assigned to receive sodium phenylbutyrate and taurursodiol (PB and TURSO) or placebo, with a 60% chance of receiving PB and TURSO and 40% chance of receiving placebo.

Participants completing the 48-week trial will have the option to enroll in an Open Label Extension (OLE) phase for up to 2 years. During this phase, all participants will receive PB and TURSO and continued safety and efficacy measures will be assessed.

OLE

About PB and TURSO

PB and TURSO, also known as AMX0035, is an investigational drug. PB and TURSO is a combination of sodium phenylbutyrate (PB) and taurursodiol (also known as ursodoxicoltaurine; TURSO). PB and TURSO is a powder that comes in packets; the powder should be mixed with water and taken by mouth or through a feeding tube.

Key Eligibility Criteria

For a list of the full eligibility criteria for the PHOENIX trial, please visit www.clinicaltrials.gov (NCT05021536). Select criteria include:

18+ Aged at least 18 years

Have started experiencing ALS symptoms within the past 24 months

Not need tracheostomy or permanent assisted ventilation (>22 hours of assisted ventilation daily for >7 days)

Have a slow vital capacity of ≥55% at the time of screening

Have been diagnosed with definite or clinically probable ALS based on revised El Escorial criteria by a physician who is experienced in management of ALS

If the participant chooses to use riluzole and/or edaravone during the course of the PHOENIX trial, they are required to be on a stable dose of these medications at the time of screening. Starting riluzole or edaravone therapy during the PHOENIX trial is not allowed

For more information about the PHOENIX trial, visit www.clinicaltrials.gov (NCT05021536) and www.clinicaltrialsregister.eu (EudraCT 2021-000250-26).

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PHOENIX

PHOENIX Trial Locations

PHOENIX is a clinical trial with sites in the United States and Europe.

Please note: Recruitment has closed in the US and is ongoing in Europe.

Sites are activating on a rolling basis; please note that listed sites may not yet be active, but will be updated once they are. The latest information is available on **www.clinicaltrials.gov**.

https://www.amylyxalstrial.com/

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