



PHOENIX

AMYLYX
Rooted in Connection

About the PHOENIX Study



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

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



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

The **PH**ase 3 **SO**dium **PhEN**ylbutyrate and Taurursodiol (Ursodo**X**icoltaurine) (PHOENIX) study will evaluate whether an investigational product called PB and TURSO is safe and effective as a treatment for adults with amyotrophic lateral sclerosis (ALS).



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.

If participants are taking a stable dose of riluzole and/or edaravone as medication for ALS before the start of the PHOENIX study, they may continue to take the medication during this study.



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 called 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.

Eligibility Criteria

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

18+

Aged at least 18 years



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

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 $\geq 55\%$ at the time of screening



If the participant chooses to use riluzole and/or edaravone during the course of the PHOENIX study, 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 study is not allowed.



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

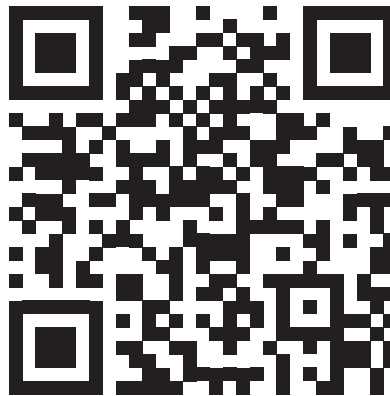


PHOENIX

PHOENIX Trial Locations

PHOENIX is a clinical trial with sites in the United States and 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.amylyxatrial.com/>