PHOENIX

AMYLYX
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About the PHOENIX Trial

The PHase 3 SOdium PhENylbutyrate-TaurursodIol (UrsodoXicoltaurine) (PHOENIX) trial will evaluate whether an investigational product called PB/TURSO is safe and effective as a treatment for adults with amyotrophic lateral sclerosis (ALS).

The PHOENIX trial is a phase 3 global trial, in which many people will be participating both 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/taurursodiol (PB/TURSO) or placebo, and neither the doctors nor the participants will know who received the investigational drug.

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

About PB/TURSO

The investigational product called PB/TURSO is a combination of sodium phenylbutyrate (PB) and taurursodiol (also called ursodoxicoltaurine; TURSO). PB/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 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.

If you meet the above criteria, you may be eligible for the PHOENIX trial. Speak with your ALS doctor or care team to review additional criteria to determine if this is the right trial for you. ***Your ALS doctor or care team can help you determine next steps in terms of trial participation.***

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

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