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Novartis ASTRALS trial

A phase 2, double-blind randomised placebo-controlled parallel-group study of VHB937 in amyotrophic lateral sclerosis (ALS) for 40 weeks followed by open-label extension.

The sponsor of the study is Novartis Pharma AG.

The aim of the study is to investigate whether the study drug, VHB937, is safe and effective, and whether it can help people with amyotrophic lateral sclerosis (ALS).

VHB937

VHB937 is an antibody that works by activating a protein that drives important brain cells called microglia to protect nerve cells. This could prevent damage to nerve cells. The aim of the study is to find out whether VHB937 is safe and slows disease progression in people with ALS who have had symptoms for no more than 2 years.

Study design

The active drug is VHB937 and you have 2 chances in 3 (66%) to receive the active drug during the first 40 weeks of the study. 1 in 3 will get a non-active treatment, i.e. a placebo.

After the first 40 weeks, each participant, if desired, will receive the active drug up to 100 weeks.

The study starts with a screening period of minimum 3 weeks to a maximum of 4 weeks. A lumbar puncture is scheduled during the screening period. During the screening period, there are a minimum of 2 hospital visits.

Then the 40 weeks double-blind part of the study starts, followed by an open label part of 60 weeks. The study medication is administered by infusion every 4 weeks throughout the treatment period.

Patients with ALS who are 18 or older, who have symptoms for a maximum of 2 years and who may or may not be treated with a stable dose of riluzole (100mg/day), have a lung function (SVC) of ≥ 60% and an ALSFRS-R score of ≥ 30, may be eligible to participate in this study.

European organization for Professionals and People with ALS (EUpALS) ivzw

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