

A Phase 3, Randomized, Multicenter, Double-Blind, Placebo-Controlled, 2-Arm, Efficacy and Safety Study of NEOD001 Plus Standard of Care Versus Placebo Plus Standard of Care in Subjects With Light Chain (AL) Amyloidosis

Clinical summary

This is a multi-center, international, randomized, double-blind, placebo-controlled, two-arm efficacy and safety study in subjects newly diagnosed with AL amyloidosis. Approximately 236 subjects will be enrolled in ~60 centers, with approximately 118 subjects per arm. This is an event driven trial, therefore subjects will remain on-study until study completion, which will occur when all primary endpoint events (all-cause mortality or cardiac hospitalizations) have been reached. All subjects who discontinue will be followed until the last event is adjudicated. The estimated overall study duration is approximately 42 months, including the enrollment and treatment periods. Study drug will be administered once every 28 days as a 60-120 minute IV infusion. First-line chemotherapy must be a proteasome inhibitor-containing regimen, with the proteasome inhibitor administered weekly. The number of cycles of first-line chemotherapy that are administered are at the discretion of the Investigator, and subsequent chemotherapy regimens may be prescribed as per standard of care at the Investigator's discretion. An independent Data Monitoring Committee (DMC) will review data on a regular basis.

Conditions

This trial is treating patients with Amyloidosis

Trial Acronym

VITAL

Cancer

Amyloidosis

Trial Identifiers

NCT02312206

NEOD001-CL002

Age: 18+

Phase: III

For full trial details, visit trials.cancervic.org.au/details/vctl_nct02312206