

A Study to Evaluate the Safety and Efficacy of SCTC21C in Combination With Bortezomib, Cyclophosphamide, and Dexamethasone in Patients With Newly Diagnosed Systemic Light-Chain Amyloidosis (NDSLCA)

NCT07388602

Status	RECRUITING
Phase	Phase 3
Sponsor	Sinocelltech Ltd.
Enrollment	90 participants

Key Eligibility Criteria

Inclusion (4)

- Histopathological diagnosis of amyloidosis based on detection by immunohistochemistry and polarizing light microscopy of green bi-refringent material in congo red stained tissue specimens or characteristic electron microscopy appearance;
- Measurable disease of amyloid light-chain (AL) amyloidosis;
- One or more organs impacted by AL amyloidosis according to consensus guidelines
- Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) 0, 1 or 2

Exclusion (7)

- Prior therapy for AL amyloidosis;
- Other amyloidosis;
- Uncontrolled infection.
- Subjects with conditions that may affect safety or efficacy assessments include, but are not limited to, cardiovascular, respiratory, endocrine/metabolic, immune system, hepatic, gastrointestinal (such as gastrointestinal bleeding, perforation, ulcers, etc.), and malignant neoplasms, and are deemed clinically significant by the investigator.
- Subjects who have undergone major surgery or experienced significant trauma within 4 weeks prior to the first use of the investigational drug, or who require elective surgery during the trial period.

... and 2 more (see full listing online)

Locations (1 total)

Peking Union Medical College Hospital, Beijing, Beijing Municipality, China