

About CRPS

Complex Regional Pain Syndrome (CRPS; also known as Reflex Sympathetic Dystrophy (RSD), algodystrophy, Morbus Sudeck, or causalgia) is a debilitating condition characterized by severe, continuous, burning or throbbing pain often occurring in an extremity after injury or surgery. The excessive pain is accompanied by changes in skin color, temperature and/or swelling. It is frequently persistent and is ranked by the McGill Pain Index as the most painful form of chronic pain that exists today. CRPS often results in loss of physical function, and can lead to significant and sometimes permanent disability. There are currently no FDA or EMA approved medications for patients with CRPS.

About Neridronate

Neridronate, an aminobisphosphonate, is a potent inhibitor of bone resorption and bone remodeling and is used in Italy in bone diseases, i.e. Paget's disease of bone and osteogenesis imperfecta. It is being developed as an intravenous, targeted, non-opioid, potentially first-in-class therapeutic for CRPS.

The pathophysiology of CRPS is to date not fully understood, but increased bone turnover may play a role by maintaining chronic inflammation in bone and surrounding tissues. Treatment with neridronate can improve or normalize CRPS related bone abnormalities.

Neridronate is an investigational medication not approved anywhere outside of Italy for treatment of CRPS.

About the trials KF7013-02 and KF7013-04

KF7013-02 and KF7013-04 are confirmatory phase III efficacy and safety trials to investigate the effect of neridronate on pain and other CRPS symptoms.

The trials are conducted at sites in the US, Canada, Germany, France, United Kingdom, Spain, Ukraine, Czech Republic, Slovakia, Poland, Serbia, Australia, New Zealand, and South Korea.

Eligible patients must be at least 18 years of age with a diagnosis of CRPS according to the 'Budapest clinical criteria'. The CRPS must not last longer than 2 years since onset of symptoms. In each trial 180 eligible patients will be randomized in a 1:1 ratio to be treated with neridronate or placebo.

The trial assesses the pain reduction after 12 weeks in comparison to placebo. In addition, the effect of neridronate vs. placebo on the pressure pain threshold, dynamic mechanical allodynia, and edema of the affected limb will be evaluated.

Further information about the trials is available on <https://clinicaltrials.gov/ct2/show/NCT03530345> and <https://clinicaltrials.gov/ct2/show/NCT03560986>.

To learn about eligibility, patients can visit <https://studycrpsnow.com/patient>.