SDN-CTR-LAYSUM-04

If you are a patient who took part in the clinical trial, thank you for your time and commitment. You made the clinical trial possible.
Thank you for helping us on our way to bringing medicines to patients.

1 TRIAL NAME

Brief trial name: Safety of intravenous neridronic acid in complex regional pain syndrome (CRPS)

Protocol number: KF7013-03

Universal trial number: U1111-1180-8099

2 WHO SPONSORED THIS TRIAL?

Grünenthal GmbH.

3 GENERAL INFORMATION ABOUT THE CLINICAL TRIAL

3.1 When was the trial?

The clinical trial began on 20 Dec 2016 and ended on 09 Jan 2019.

3.2 What was the main objective of the trial?

The main aim of this trial was to investigate the safety of neridronic acid given as an infusion into the vein of patients with CRPS.

4 WHICH PATIENTS WERE INCLUDED IN THIS TRIAL?

4.1 Where did the patients take part in the trial?

The clinical trial took place in these countries:

EU countries

- Germany (8 patients)

Non-EU countries

- United States (308 patients)

A total of 316 patients were treated with neridronic acid in the clinical trial.

4.2 How old were the patients?

The youngest patient was 19 years old and the oldest patient was 77 years old. The average (mean) age was 47 years.

4.3 Were the patients men or women?

237 patients were female and 79 patients were male.

4.4 Which patients were able to take part in the trial?

Patients were only able to take part in the clinical trial if they met certain criteria. This was important to make sure that it was safe for each patient to take part in the clinical trial, that the results of the clinical trial were valid, and that the laws and regulations were followed.

Patients who took part had CRPS. Every patient had been on stable treatment for CRPS for at least 1 month before the start of the clinical trial. Each patient had to have at least 2 previous failed alternative treatments for CRPS. One of these treatments had to be a medicine.

5 WHICH MEDICINES WERE STUDIED?

Each patient received neridronic acid during the trial. Neridronic acid is a medicine being tested for treating CRPS. It belongs to a group of medicines already used to treat other conditions (for example, softening of the bones [“osteoporosis”]).

Patients were given 100 mg of neridronic acid as a slow infusion into a vein 4 times over a period of 10 days. The total planned dose of neridronic acid was 400 mg.

6 WHAT WERE THE OVERALL RESULTS OF THE TRIAL?

The trial was designed to investigate the safety of neridronic acid. As a result, no conclusions can be made about how well neridronic acid eased pain or other symptoms of CRPS.

Patients were observed for up to 1 year after receiving neridronic acid. During this time, almost 9 out of 10 patients reported unwanted effects. 6 out of 10 patients experienced unwanted effects which the trial doctor thought could be side effects of neridronic acid.

The most common side effects were headache, muscle aches, feeling sick, pain, and tiredness.

The safety of neridronic acid when given into a vein of CRPS patients was found to be in line with what was already known about neridronic acid.

The results described in this report are for one clinical trial. The findings of other clinical trials might be different. How well neridronic acid works and how safe it is to use must not be judged on the results of one clinical trial alone.

If you have questions, please contact your family doctor.