You should not use this summary to make decisions about the medical treatments you use.
You should always see your doctor for advice about medical treatments.

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.
You helped us on our way to bringing new medicines to patients.

1 TRIAL NAME

Brief trial name: A clinical trial to find out if neridronic acid given into a vein eases the pain felt by patients who have complex regional pain syndrome type I (CRPS-I)

Full trial name: A randomized, double-blind trial investigating the efficacy and safety of intravenous neridronic acid in subjects with complex regional pain syndrome type I (CRPS-I)

Protocol number: KF7013-01

Universal trial number: U1111-1151-2181

2 WHO SPONSORED THIS TRIAL?

Sponsor: Grünenthal GmbH

3 GENERAL INFORMATION ABOUT THE CLINICAL TRIAL

3.1 When was the trial?

The clinical trial began on 01 Apr 2015 and ended on 02 Nov 2016.

3.2 What was the main objective of the trial?

CRPS-I patients feel bad pain in their affected limb all of the time. The main aim of this clinical trial was to find out if CRPS-I patients who are given neridronic acid into a vein feel that their pain is

eased more than CRPS-I patients who are given dummy medicine into a vein. Another aim was to find out if neridronic acid is safe to be given to CRPS-I patients in this way.

The trial explored the relationship between the amount of neridronic acid given and the amount of pain relief. The trial also aimed to find the smallest amount of neridronic acid needed to ease pain.

Future trials will be performed with a higher dose of neridronic acid to confirm that it eases pain and is safe.

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 (11 patients)
- Great Britain (2 patients)

Non-EU countries

- USA (217 patients)

A total of 230 patients were treated with neridronic acid or dummy medicine in the clinical trial.

4.2 How old were the patients?

The average (mean) age was 45 years. The youngest patient was 18 years old and the oldest patient was 77 years old.

4.3 Were the patients male or female?

176 patients were female and 54 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 to follow laws and regulations.

Patients who took part had CRPS-I. Every patient had been on stable treatment for CRPS-I for at least 1 month before the start of the clinical trial.

5 WHICH MEDICINES WERE STUDIED?

- Neridronic acid is the test medicine for treating CRPS-I. It belongs to a group of medicines already used to treat other conditions (for example, softening of the bones [“osteoporosis”]).
- Placebo (dummy medicine). It looks like a proper medicine but does not contain any active ingredients. This was used to distinguish real effects of the medicine from effects that can come from, for example, expectations and hopes of improvement.

Patients were given trial medicine into a vein 4 times over a period of 10 days. Patients had an equal chance of being given any of 3 treatments: a total of 250 mg neridronic acid, a total of 125 mg neridronic acid, or dummy medicine.

The amounts of neridronic acid given were lower than in previous trials where pain relief was seen so that the relationship between the amount of medicine and the amount of pain relief could be explored.

Neither doctors nor patients knew which patients were given which medicine. This was to make sure that the results of the clinical trial were fair.

6 WHAT WERE THE OVERALL RESULTS OF THE TRIAL?

In the 12 weeks after first being given trial medicine, each patient was asked twice a day every day how much pain they felt in their affected limb at that moment.

How much pain each patient felt in their affected limb during the twelfth week after being given trial medicine was compared to their average pain during the first week. In the twelfth week, there was no difference in pain relief between the 3 treatments (250 mg of neridronic acid, 125 mg of neridronic acid, or dummy medicine).

3 out of 4 patients had side effects. The number of patients with side effects was about the same in the 3 treatment groups. The safety of neridronic acid when given into a vein of a CRPS-I patient 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 trial doctor.