

## CASE STUDY

### **Randomized controlled trial in adults with headache recurrence after emergency department discharge, comparing the efficacy of oral sumatriptan to naproxen**

#### **CATEGORISING**

**Kind**

Research project involving living people

**Type**

Clinical trial

**Subtype**

Clinical trial with medicinal products (including combinations according to Art. 2 Para. 1 Letters f and g MedDO)

#### **BACKGROUND**

Migraine and other acute primary headaches are treated with a variety of parenteral medications in the emergency department. It is not clear which medication is best to prescribe to primary headache patients when they are discharged. This study compared the efficacy of oral sumatriptan to naproxen for treatment of post-ED recurrent primary headache.

#### **METHODS**

Adults aged 18 years or older who suffered from headache recurrence after discharge from an emergency department were randomized to either naproxen (Trade®) 500 mg or sumatriptan (Sumatriptan Spirig HC®) 100 mg. This was an open trial: patients and physicians knew who was given which medication. Both products were provided in the original package. The packages had trial-specific labels and were handed out by a hospital pharmacist. Patients were followed-up by telephone 48 hours after emergency department discharge. The primary outcome was change in pain intensity, measured during a two-hour period after ingestion. The change in the group that received 500 mg naproxen (Trade®) was compared to the change in the group that received 100 mg sumatriptan (Sumatriptan Spirig HC®). This difference was measured on a validated 11-point (0–10) verbal Numerical Rating Scale (NRS).

#### **QUESTIONS OF THE CATEGORISER**

**Does the research project come under the scope of application of the Human Research Act?**

Yes

**BECAUSE**

This project was based on a study protocol which defined the exact procedures to be used. The study is designed to answer a disease related research question. It includes a relatively large number of persons and is not based on individual cases ("method-driven search for generalizable knowledge"); thus, it is classified as research according to HRA). Adults ("persons") who suffered from headache ("research concerning human diseases") after discharge from an emergency department were treated with either 500 mg naproxen (Trade®) or 100 mg sumatriptan (Sumatriptan Spirig HC®).

**Is the research project a project involving living persons?**

Yes

**BECAUSE**

Adults ("persons") who suffered from headache after discharge from an emergency department were included in this research project.

**Is the research project a clinical trial?**

Yes

**BECAUSE**

In this research project, the investigator randomly assigned ("prospectively assigned") adults ("persons") who suffered from headache after discharge from an emergency department to receive either 500 mg naproxen (Trade®) or 100 mg sumatriptan (Sumatriptan Spirig HC®) ("health related intervention (therapeutic measure)"). The project assessed between-group difference in change in in pain intensity over the 2-hour period after they took the drugs ("to investigate its effect on health").

**Does the trial involve investigating medicinal products (including combinations according to Art. 2 Para. 1 Letters f and g Medical Device Ordinance (MedDO) from the July 1, 2020)?**

Yes

**BECAUSE**

This clinical trial investigated the effects of naproxen (Trade®) 500 mg and sumatriptan (Sumatriptan Spirig HC®) 100 mg. (Both are "medicinal products").

**Is the IMP authorised in Switzerland?**

Yes

**BECAUSE**

This clinical trial investigated the effects of naproxen (Trade®) 500 mg and sumatriptan (Sumatriptan Spirig HC®) 100 mg. Both are "authorised" for the market in Switzerland, and are provided "as is", unchanged except for their labels. (Approval numbers for sumatriptan/[Sumatriptan Spirig HC®]: 58466, 58512, 58513 [Swissmedic]; and, for naproxen/[Trade®]: 51480 [Swissmedic]).

**Does the IMP administration comply with the specifications in the summary of product characteristics (SPC)?**

Yes

**BECAUSE**

This clinical trial investigated the effects of naproxen (Trade®) 500 mg and sumatriptan (Sumatriptan Spirig HC®) 100 mg on patients who suffered from headache after discharge from an emergency department. Naproxen and sumatriptan are approved in Switzerland for the treatment of headache. According to the summary of product characteristics , the maximum recommended dose for naproxen (Trade®) is 500 mg a day. For Sumatriptan (Sumatriptan Spirig HC®) it is 200 mg a day. Summary of product characteristics available here.

**Is a placebo used in the trial, or is the original status of the medicinal product or its packaging as approved by Swissmedic modified?**

No

**BECAUSE**

This clinical trial investigated the effects of naproxen (Trade®) 500 mg and sumatriptan (Sumatriptan Spirig HC®) 100 mg. Both are "authorised" for the market in Switzerland, and are provided "as is". The medicinal product was provided in its original package but labelled with a trial-specific sticker (label). However, the label did not cover any pharmaceutically relevant information. This modification is not manufacturing according to the Therapeutics Product Act (TPA).