# Sumatriptan non-responders: evaluation of a possible biomarker

Published: 13-09-2012
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To find a simple test to explain non-responsiveness to sumatriptan in a proportion of patients with migraine.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Headaches |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON39452

**Source**
ToetsingOnline

**Brief title**
SNEB

### Condition

- Headaches

**Synonym**
Migraine

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Hersenstichting Nederland

### Intervention

**Keyword:** Capsaicin, Iontophoresis, Migraine, Sumatriptan

## Outcome measures

### Primary outcome

Changes in dermal blood flow response to capsaicin application en saline

iontophoresis, after sumatriptan administration.

### Secondary outcome

Blood pressure changes after sumatriptan use.

# Study description

### Background summary

The introduction of triptans approximately 20 years ago was a great improvement in the treatment of migraine. Unfortunately with triptans not all migraine patients can be treated successfully. The cause of this treatment failure is not clear yet. We hope to determine the cause by measuring with a laser Doppler scanner the increase in dermal blood flow (DBF) after stimulation of the afferent nerves of the trigeminal nerve on the forehead. The trigeminal nerve also innervates the dura mater, where the migraine is thought to have its origin. The trigeminal afferent nerves will be stimulated by topical application of capsaicin and electrical stimulation via iontophoresis of saline. Both stimuli lead to release of the vasodilator neuropeptide CGRP. In a pilot study we have shown that these stimuli indeed increase DBF. We think that in migraine patients with a good clinical response to sumatriptan the release of CGRP is inhibited, but in patients with a poor or absent clinical response to sumatriptan the CGRP release is not blocked. We will investigate this hypothesis with the above mentioned model. First we will perform a study with healthy volunteers and in future this study will be performed in migraine patients with a consistently good or absent response to sumatriptan. This study will provide more insight in the action of sumatriptan resulting in more personalised treatment of patient with migraine.

### Study objective

To find a simple test to explain non-responsiveness to sumatriptan in a proportion of patients with migraine.

### Study design

A randomised double blind controlled crossover study

### Intervention

Sumatriptan succinate 6 mg/ 0,5 ml (which is the normal therapeutic dose) subcutaneously.

### Study burden and risks

The amount of time consumed by this research and the side effects of sumatriptan are the burden. Capsaicin application can cause temporary redness and some irritation of the skin.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Age between 18 and 50 years
Non-smoking for > 6 months
Body mass index between 18 and 30 kg/m^2
Capable and willing to give informed consent
General good health, based on medical history and physical examination

### Exclusion criteria

History of cardiovascular disease
Any serious illness that can compromise study participation
Use of any medication (e.g., NSAIDs, other analgesics); 48 hrs before the study
Dermal diseases at the upper frontal side of the face
Pregnancy or breastfeeding;History of sensitivity to the fruits of capsicum plants (e.g. chilli peppers);Alcohol or drug abuse

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 10-09-2013 |
| Enrollment: | 21 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Imigran Injection |
| Generic name: | Sumatriptansuccinate |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | Sodium Chloride 0.9% solution for injection |
| Generic name: | Sterile Saline Solution (0.9%) |
| Registration: | Yes - NL outside intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 13-09-2012 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 29-10-2012 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 11-07-2013 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 19-08-2013 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

## Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2011-005256-34-NL |
| CCMO | NL38589.078.12 |