

# Triptan overuse in migraine in primary care, a proactive approach

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Headaches
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON30289

### Source

ToetsingOnline

### Brief title

LIMIT-study

Leiden Improvement of Migraine Therapy in general practice

### Condition

- Headaches

### Synonym

migraine

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** ZonMw;doelmatigheidsfonds,Stichting Nuts Ohra

## Intervention

**Keyword:** disease management, Migraine disorders, prevention and control

## Outcome measures

### Primary outcome

Reduction of score on the HIT-6 questionnaire (measuring headache impact) at six months after the start of the intervention.

### Secondary outcome

HIT-6 questionnaire at 3 and 12 months follow up

\*migraine frequency (diary over 1 month as used in Dutch General Practice, to be filled in at baseline and follow up moments)

\*quality of life (questionnaires: visual analogue scale and societal EQ-5D)

\*triptan/analgesic use (information from prescriptions registered in EPR)

\*prophylactic medication (information from prescriptions registered in EPR)

## Study description

### Background summary

Migraine is characterized by recurrent attacks of disabling headaches, in 25 % associated with vomiting and hypersensitivity to light, sound and smell (1;2). Migraine can be treated with analgesics and anti-emetics or with triptans. Triptans are an adequate but expensive intervention. Over consumption of triptans is applied by 13% of the triptan users and can lead to an increase in headache frequency. Moreover, although approximately 60 % of the patients have one or more attacks per month, only 5% use prophylactic treatment (3).

### Study objective

The aim of the study is to optimize therapy of migraine patients, according to the Dutch GP Guideline for headache and consequently reduce the use of triptans. The project will explore the costs and effects of a proactive approach of patients with triptan use by GPs. Proactive approach includes

selecting patients with  $\geq 24$  DDD triptan use (or  $\geq 6$  DDDs in the last 3 months) from the Electronic Patient Records and inviting them by mail for consultation. After verifying the migraine diagnosis, a treatment strategy is implemented aiming to optimise migraine therapy. We will investigate whether contacting triptan users and subsequently give them advice about migraine therapy, will lead to a lower headache frequency, less severe headache and associated improved quality of life. Additionally we will investigate changes in triptan use and the costs involved in this intervention.

## **Study design**

Cluster randomized controlled trial; randomization will be performed on practice level.

## **Intervention**

Proactive stepped approach based on the Dutch GP Guideline versus usual care. Step 1: a letter to invite patients for consultation. Step 2: a visit to the GP, who can give information about headache and therapy, reduce/stop the triptans, prescribe prophylactic therapy or reconsider the diagnosis of migraine. Follow-up at 0, 3, 6 and 12 months by using the questionnaires, EPR and calendars.

## **Study burden and risks**

Burden: participants are asked to fill in 2 short questionnaires and a diary over 1 month at 4 moments during the follow up. Participants in the intervention practices are invited for a consultation and subsequently an average of two consultations during the follow up period will follow.

Risk: no risks are involved in this project.

## **Contacts**

### **Public**

Leids Universitair Medisch Centrum

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NL

### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

1. registered in Electronic Patient Register of the GP
2. prescriptions for triptans, dosed 24 doses or more per year (or 6 or more daily doses in the last 6 months)

### Exclusion criteria

younger than 18 years old  
cognitive impairment  
psychiatric illness  
end-stage of a malignant disease  
non-Dutch speaking

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking: Single blinded (masking used)

**Primary purpose:** Health services research

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-03-2007  
Enrollment: 600  
Type: Anticipated

## Ethics review

Approved WMO  
Application type: First submission  
Review commission: METC Leids Universitair Medisch Centrum (Leiden)

## 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
Other	kandidaat trial ntr 2367
CCMO	NL15260.058.06