

# Leiden Improvement of Migraine Therapy in general practice

<b>Submission date</b> 22/01/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/05/2012	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

## Acronym

LIMIT-study

## Study objectives

The aim of the study is to optimise therapy of migraine patients, according to the Dutch General Practitioner (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.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised, controlled, parallel group, multicentre trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

GP practice

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Migraine

## Interventions

Intervention:

Proactive stepped approach based on the Dutch GP Guideline:

Step one: a letter to invite patients for consultation.

Step two: 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.

Control group:  
Care as usual.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

Headache Impact Test (HIT-6) score at baseline and after three, six, nine and 12 months.

## **Secondary outcome measures**

1. The health-related quality of life (self reported EuroQoL [EQ-5D] questionnaire and visual analogue scale)
2. Migraine characteristics
3. Medication use
4. Social effects of migraine including absence at work

Measured at baseline and after three, six, nine and 12 months.

## **Overall study start date**

01/03/2007

## **Completion date**

01/03/2010

# **Eligibility**

## **Key inclusion criteria**

Patients in general practice using more than or equal to 24 Defined Daily Doses (DDD) triptans (or more than or equal to six DDDs in the last three months), enlisted in 60 general practices, that are part of LEON (Leiden Eerstelijns OnderzoeksNetwerk), managed by the department of Public Health and Primary Care.

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Sex**

Not Specified

## **Target number of participants**

600

## **Key exclusion criteria**

1. Younger than 18 years
2. Cognitive impairment
3. Psychiatric illness
4. Terminal illness
5. Non-Dutch speaking

**Date of first enrolment**

01/03/2007

**Date of final enrolment**

01/03/2010

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Leiden University Medical Center (LUMC)**

Leiden

Netherlands

2300 RC

## **Sponsor information**

**Organisation**

Leiden University Medical Center (LUMC) (The Netherlands)

**Sponsor details**

Department of Public Health and Primary Care

P.O. Box 9600

Leiden

Netherlands

2300 RC

**Sponsor type**

Hospital/treatment centre

**Website**

[http://www.lumc.nl/english/start\\_english.html](http://www.lumc.nl/english/start_english.html)

**ROR**

<https://ror.org/05xvt9f17>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Stichting Nuts Ohra (The Netherlands)

## Funder Name

Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

## Alternative Name(s)

Netherlands Organisation for Health Research and Development

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Other non-profit organizations

## Location

Netherlands

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	06/03/2012		Yes	No