ISRCTN72421511 https://doi.org/10.1186/ISRCTN72421511

Leiden Improvement of MIgraine Therapy in general practice

Submission date	Recruitment status	[X] Prospectively registered
22/01/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/01/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/05/2012	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J W Blom

Contact details
Leiden University Medical Center (LUMC)
Department of Public Health and Primary Care
Postzone V-0-P
P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 526 8406
J.W.Blom@lumc.nl

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

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?
Results article	results	06/03/2012		Yes	No