Leiden Improvement of Migraine Therapy in general practice.

No registrations found.

Ethical review Not applicable **Status** Recruiting

Health condition type -

Study type Interventional

Summary

ID

NL-OMON24827

Source

NTR

Brief title

LIMIT-study

Health condition

migraine

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

HIT-6 (Headache Impact Test)-score at baseline and after 3, 6, 9 and 12 months.

Secondary outcome

- 1. The health-related quality of life (self reported EQ-5D and visual analogue scale);
 - 1 Leiden Improvement of Migraine Therapy in general practice. 5-05-2025

- 2. Migraine characteristics;
- 3. Medication use:
- 4. Social effects of migraine including absence at work.

Measured at baseline and after 3, 6, 9 and 12 months.

Study description

Background summary

We aim to study the costs and effects of a pro-active approach of migraine patients by the General Practitioner. The design is a pragmatic cluster randomised controlled trial with the general practice as the unit of randomisation. Patients using >=24 DDD's triptans are selected from the EMD and invited by mail to consult their GP. Diagnosis and treatment plan of migraine will be evaluated and discussed. Patients will be offered prophylactic treatment according to the Dutch Guidelines (NHG-standaard). The control group will receive usual care. The primary outcome is the score on the HIT-6 questionnaire.

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.

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.

Control group: care as usual.

Contacts

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Scientific

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Eligibility criteria

Inclusion criteria

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Patients in general practice using ¡Ý24 DDD triptans (or ¡Ý6 DDDs in the last 3 months), enlisted in 60 general practices, that are part of LEON (the Leiden Eerstelijns Onderzoeksnetwerk, managed by the department of Public Health and Primary Care).

Exclusion criteria

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

Study design

Design

Study type: Interventional

Intervention model: Parallel

Masking: Open (masking not used)

Control: Active

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-03-2007

Enrollment: 600

Type: Anticipated

Ethics review

Not applicable

Application type: Not applicable

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

NTR-new NL827 NTR-old NTR840 Other : N/A

ISRCTN ISRCTN72421511

Study results

Summary results

N/A