Triptan overuse in migraine in primary care, a proactive approach

Published: 16-07-2007
Last updated: 09-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Headaches
Study type	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 >=24 DDD triptan use (or >=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 advise 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

Postbus 2088
2301 CB Leiden
NL
Scientific
Leids Universitair Medisch Centrum

Postbus 2088

2301 CB Leiden
NL

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