PREvention of Migraine In Adolescents

Submission date	Recruitment status	Prospectively registered
28/12/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/12/2006	Completed	Results
Last Edited	Condition category	Individual participant data
29/12/2006	Nervous System Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr D Noordzij

Contact details

Erasmus Medical Centre Department of General Practice Westzeedijk 112-114 Alkmaar Netherlands 3016 AH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Acronym

PREMIA

Study objectives

Based on systematic reviews concerning effective treatments in children with migraine a medical treatment (propanolol) as well as a non-medical treatment (relaxation therapy) appear to be effective compared to no treatment or placebo. However their relative effectiveness is unknown.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, placebo controlled, parallel group, triple blinded trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Migraine

Interventions

Group 1: Propanolol treatment and placebo relaxation treatment

Group 2: Placebo medical treatment and relaxation therapy

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Propanolol

Primary outcome measure

- 1. Perceived effect and change of intensity
- 2. Frequence and duration of migraine attacks

Secondary outcome measures

- 1. Change in 'quality of life'- experience
- 2. Number of schooldays missed
- 3. Medical consumption

Overall study start date

01/10/2006

Completion date

31/07/2007

Eligibility

Key inclusion criteria

- 1. Migraine patients
- 2. Aged 13 to 18 years
- 3. Living in Rotterdam

Participant type(s)

Patient

Age group

Child

Lower age limit

13 Years

Upper age limit

18 Years

Sex

Not Specified

Target number of participants

160

Key exclusion criteria

- 1. Patients suffering from asthma, allergies and diabetes
- 2. Using propanolol and/or relaxation therapy as a treatment less then six months before the start of the trial

Date of first enrolment

01/10/2006

Date of final enrolment

31/07/2007

Locations

Countries of recruitment

Netherlands

Study participating centre Erasmus Medical Centre

Alkmaar Netherlands 3016 AH

Sponsor information

Organisation

Erasmus Medical Center (The Netherlands)

Sponsor details

Department of General Practice P.O. Box 1738 Rotterdam Netherlands 3000 DR

Sponsor type

Hospital/treatment centre

Website

http://www.erasmusmc.nl/#http://www.erasmusmc.nl/

ROR

https://ror.org/018906e22

Funder(s)

Funder type

Other

Funder Name

Nuts/Ohra (The Netherlands)

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration