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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

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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 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