ISRCTN33364178 https://doi.org/10.1186/ISRCTN33364178

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

Protocol serial number
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

Study type(s)
Treatment

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(s)
1. Perceived effect and change of intensity
2. Frequence and duration of migraine attacks

Key secondary outcome(s))
1. Change in 'quality of life'- experience
2. Number of schooldays missed
3. Medical consumption

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 years

Upper age limit
18 years

Sex
Not Specified

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)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Other

Funder Name
Nuts/Ohra (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration