

PREvention of Migraine In Adolescents

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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. Frequency 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 propranolol and/or relaxation therapy as a treatment less than 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