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Preventing migraine in children and young people

Submission date	Recruitment status	[X] Prospectively registered
25/09/2008	Stopped	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/10/2008	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/01/2012	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
HTA 05/15/01; 29372

Study information

Scientific Title
A double-blind parallel-group randomised placebo-controlled trial of propranolol and pizotifen in preventing migraine in children

Acronym
P3MC

Study objectives
1. Propranolol is superior to placebo for the prevention of migraine attacks in children aged 5 - 16 years
2. Pizotifen is superior to placebo for the prevention of migraine attacks in children aged 5 - 16 years

More details can be found at http://www.hta.ac.uk/1526
Protocol can be found at http://www.hta.ac.uk/protocols/200500150001.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Trent Research Ethics Committee (REC) approved in November 2008 (ref: 09/H0405/19)

Study design
Parallel-group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Paediatric migraine

Interventions
Eligible participants will be randomly allocated to the following four arms after the 4-week run-in period, double blind:

Arm 1 (n = 200): Propranolol (oral; tablet or liquid):
Children aged 5 - 7:
Week 1: 10 mg twice daily (bd)
Week 2: 20 mg bd
Week 3 - 14: 30 mg bd

Children aged 8 - 11:
Week 1: 20 mg bd
Week 2: 30 mg bd
Week 3 - 14: 40 mg bd

Children aged 12 - 16:
Week 1: 30 mg bd
Week 2: 40 mg bd
Week 3 - 14: 60 mg bd

Week 15 - 16: Dose of the drug will be reduced gradually before stopping completely

Arm 2 (n = 200): Pizotifen (oral; tablet or liquid):
Children aged 5 - 7:
Week 1: placebo + pizotifen 500 µg once daily (od)
Week 2: placebo + pizotifen 1 mg od
Week 3 - 14: placebo + pizotifen 1.5 mg od

Children aged 8 - 11:
Week 1: placebo + pizotifen 1 mg od
Week 2: placebo + pizotifen 1.5 mg od
Week 3 - 14: placebo + pizotifen 2 mg od

Children aged 12 - 16:
Week 1: placebo + pizotifen 1.5 mg od
Week 2: placebo + pizotifen 2 mg od
Week 3 - 14: placebo + pizotifen 3 mg od

Week 15 - 16: Dose of the drug will be reduced gradually before stopping completely

Arm 3 (n = 100): Propranolol placebo control group

Arm 4 (n = 100): Pizotifen placebo control group

Amended as of 11/01/2012, the trial was stopped early due to poor recruitment at the end of June 2011.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Propranolol, pizotifen

Primary outcome measure
Number of migraine attacks during weeks 11 to 14

Secondary outcome measures
1. Response defined as a 50% or greater reduction in number of attacks. Duration of follow-up: 42 weeks.
2. Headache intensity (headache diary). Duration of follow-up: 14 weeks.
3. Use of rescue medication. Duration of follow-up: 14 weeks.
4. School attendance. Duration of follow-up: 14 weeks.
5. Parent/guardian time off work during weeks 11 to 14
6. Recalled attack frequency. Duration of follow-up: 14 weeks.
7. Quality of life and functional outcomes: Paediatric Migraine Disability Assessment (PedMIDAS), Generic Child Quality of Life measure (GCQ), parent Euroqol EQ-5D, child Euroqol EQ-5D

Overall study start date
01/06/2009

Completion date
01/07/2012

Reason abandoned (if study stopped)
"Participant recruitment issue"

Eligibility

Key inclusion criteria
1. Both males and females, age 5 years 0 months to 16 years 11 months
2. With Migraine with Out aura (MO), Migraine with Aura (MA), Probable Migraine (PM) as defined by the International Headache Society (IHS1) criteria, with 2 to 6 migraine or probable migraine attacks/ 4 weeks by history during the previous 3 months
3. Two to 6 migraine or probable migraine attacks/ 4 weeks during the 4 week run-in
4. Treating paediatrician and parent/ guardian and child or young person believe the attacks are currently frequent and severe enough to merit a try of twice daily preventative medication
5. Satisfactory completion of headache diary during the run-in period at discretion of the investigator

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
16 Years

Sex

Not Specified

Target number of participants
600 (Poor recruitment, study stopped at the end of June 2011)

Key exclusion criteria
Amended as of 13/07/2009:
1. Asthma, bronchospasm or nocturnal or exercise induced cough or wheeze within the last 12 months or currently on daily asthma preventative treatment
2. Children under paediatric cardiology review, at the discretion of their paediatric cardiologist, e. g. if propranolol or pizotifen were contraindicated
3. Children with any of the following: uncontrolled heart disease, the presence of second or third degree heart block, in cardiogenic shock, bradycardia, severe peripheral arterial disease, metabolic acidosis, sick sinu syndrome, untreated phaeochromocytoma, prone to hypoglycaemia (e.g. after prolonged fasting) or Prinzmetal's angina
4. Previous severe adverse event probably related to propranolol or pizotifen
5. On propranolol, another beta-blocker, pizotifen or cyproheptidine in the last 3 months
6. Currently in or have been in another prospective drug trial in the last 3 months
7. Fewer than two or more than six eligible attacks during the 4 week run-in, and stay excluded for 3 months at least
8. Child or family unable to identify their migraine or probable migraine headaches confidently (as may happen with some patients with both mild headaches and migraine on different days, e. g. with chronic daily headache [15 or more headache days/month])
9. Females of child bearing potential who are not using a reliable contraceptive strategy such as abstinence, barrier methods, oral contraceptive pills and contraceptive injections
10. Informed consent not given by parents/guardian, or assent/consent not given by patient

Initial information at time of registration:
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Date of first enrolment
01/06/2009

Date of final enrolment
01/07/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Nottingham
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Research Innovation Services
King's Meadow Campus
Lenton Lane
Nottingham
England
United Kingdom
NG7 2NR

Sponsor type
University/education

Website
http://www.nottingham.ac.uk

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/06/2010		Yes	No
HRA research summary			28/06/2023	No	No