ISRCTN35114412 https://doi.org/10.1186/ISRCTN35114412

Clopidogrel as prophylactic treatment for migraine

Submission date	Recruitment status	[X] Prospectively registered
21/03/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/11/2014	Nervous System Diseases	

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
Version 05

Study information

Scientific Title

Study objectives
That clopidogrel is effective for the prophylaxis of migraine with or without the presence of a patent foramen ovale.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from Guy's Hospital Ethics Committee on the 17th December 2007 (ref: 07/H0804/139).

Study design
Randomised placebo-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
Migraine

Interventions
1. Clopidogrel 75 mg orally once daily to be taken for three months
2. Placebo

The study has a one month run-in prior to treatment. After the three month treatment there is no further follow-up.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Clopidogrel

Primary outcome measure
The number of headache-free days in one month (28 days). Migraine will be assessed using a headache diary kept for 28 days during run-in then again for the final 28 days of the three-month treatment period.

Secondary outcome measures
1. Frequency of attacks
2. Severity of attacks
3. Duration of attacks

Migraine will be assessed using a headache diary kept for 28 days during run-in then again for the final 28 days of the three-month treatment period. In addition the patients will have the 6-item Headache Impact Test (HIT-6) and Migraine Disability Assessment (MIDAS) questionnaires at the start and end of the study.

Overall study start date
01/05/2008

Completion date
30/04/2011

Eligibility

Key inclusion criteria
1. Age greater than 18 years, either sex
2. Migraine as defined by International Headache Criteria
3. More than two attacks in 28 days

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
286

Key exclusion criteria
1. High risk features suggesting cerebral malignancy
2. Contra-indications to clopidogrel
3. Requirements for routine non-steroidal anti-inflammatory agent or aspirin other than for acute headache

4. Use of an investigational product within three months
5. Inability to understand English
6. Pregnancy or breast-feeding
7. Abnormal platelet or liver function

Date of first enrolment
01/05/2008

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cardiothoracic Centre
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's and St Thomas NHS Trust (UK)

Sponsor details
Westminster Bridge Road
London
England
United Kingdom
SE1 7EH

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
The Dunhill Medical Trust (UK)

Funder Name
Sanofi-Aventis (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?
Results article	results	01/12/2014		Yes	No
HRA research summary			28/06/2023	No	No