# Clopidogrel as prophylactic treatment for migraine

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

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

### Type(s)

Scientific

#### Contact name

Dr John Chambers

#### Contact details

Cardiothoracic Centre St Thomas Hospital Westminster Bridge Road London United Kingdom SE1 7EH

#### 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	<b>Details</b> results	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2014		Yes	No
HRA research summary			28/06/2023	No	No