

The effects of homocysteine-lowering vitamin supplementation on migraine disability

Submission date 29/11/2007	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 18/12/2007	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 18/12/2007	Condition category Nervous System Diseases	☐ Individual participant data
		☐ 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

Study information

Scientific Title

Study objectives

Does vitamin therapy including folic acid reduce homocysteine and migraine disability, and is the effect dependent on MTHFR genotype?

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the Griffith University Ethics Committee on 11 November 2005 (ref: 3425)

Primary study design

Interventional

Study design

Randomized controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Migraine with aura

Interventions

Daily B vitamin (B6, B9, B12) therapy vs placebo for 6 months

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Migraine disability, as measured using the Migraine Disability Assessment (MIDAS) score at baseline and 6 months.

Key secondary outcome(s)

1. Migraine frequency. Duration of follow-up: 6 months
2. Migraine pain: MIDAS pain score 1-10 (10 = most severe) at baseline and 6 months

Completion date

30/11/2007

Eligibility

Key inclusion criteria

1. Current diagnosis of regular migraine with aura attacks
2. >18 and <70 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Co-morbid vascular or neuropsychiatric disease
2. Pregnant
3. Currently taking B vitamins

Date of first enrolment

30/11/2006

Date of final enrolment

30/11/2007

Locations**Countries of recruitment**

Australia

Study participating centre

Griffith University

Gold Coast

Australia

9726

Sponsor information**Organisation**

Griffith University (Australia)

ROR

<https://ror.org/02sc3r913>

Funder(s)**Funder type**

Research organisation

Funder Name

Brain Foundation of Australia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration