# Comparative study of the efficacy and safety of intranasal ketamine and midazolam for the acute treatment of migraine with prolonged aura

Submission date	Recruitment status	[] Prospectively	
12/09/2003	No longer recruiting	[_] Protocol	
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	[] Statistical ana	
		[X] Results	
Last Edited 06/12/2013	<b>Condition category</b> Nervous System Diseases	[_] Individual part	

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- rticipant data

### Plain English summary of protocol

Not provided at time of registration

### Contact information

#### Type(s) Scientific

Contact name Dr PJ Goadsby

#### **Contact details**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0263104924

### Study information

Scientific Title

#### **Study objectives**

A comparative study of the efficacy and safety of intranasal ketamine and midazolam for the acute treatment of migraine with prolonged aura and familial hemiplegic migraine.

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** Not provided at time of registration

**Study design** Randomised controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Not specified

**Study type(s)** Not Specified

Participant information sheet

Health condition(s) or problem(s) studied Migraine

**Interventions** Clinical trial: 1. Intranasal ketamine 2. Midazolam

**Intervention Type** Other

**Phase** Not Specified

Primary outcome measure

Patient diary-based observations of progression of aura

**Secondary outcome measures** Not provided at time of registration

Overall study start date 01/09/2001

Completion date 01/12/2005

### Eligibility

**Key inclusion criteria** 30 Patients from Neurology.

Participant type(s) Patient

Age group Not Specified

**Sex** Not Specified

**Target number of participants** 30

**Key exclusion criteria** Not provided at time of registration

Date of first enrolment 01/09/2001

Date of final enrolment 01/12/2005

### Locations

**Countries of recruitment** England

United Kingdom

Study participating centre

**Headache and Migraine Group** London United Kingdom WC1N 3BG

### Sponsor information

**Organisation** Department of Health (UK)

**Sponsor details** Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type Government

Website http://www.doh.gov.uk

### Funder(s)

**Funder type** Government

**Funder Name** University College London Hospitals NHS Trust (NHS R&D Support Funding)

### **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?
<u>Results article</u>	results	12/02/2013		Yes	No