

# Intranasal zolmitriptan is effective and well tolerated in acute cluster headache

<b>Submission date</b> 14/02/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/02/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/08/2008	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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**Contact details**  
Institute of Neurology  
University College London  
London  
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WC1N 3BG

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
ZINCH-1

## Study information

**Scientific Title**

**Acronym**

ZINCH

**Study objectives**

Zolmitriptan intranasal is more effective than placebo in the treatment of acute cluster headache.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval received from the National Hospital for Neurology and Neurosurgery Ethics Committee on the 8th May 2003 (ref: 02/N031).

**Study design**

Randomised, placebo-controlled, double-blind cross-over trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Cluster headache

**Interventions**

Zolmitriptan nasal spray versus placebo.

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Zolmitriptan

**Primary outcome measure**

Proportion of patients who have taken active drug with headache relief at 30 minutes.

**Secondary outcome measures**

Pain free at 30 minutes.

**Overall study start date**

01/09/2003

**Completion date**

01/01/2005

**Eligibility****Key inclusion criteria**

Cluster headache with attacks longer than 45 minutes.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

90

**Key exclusion criteria**

Contraindications to zolmitriptan in participating countries.

**Date of first enrolment**

01/09/2003

**Date of final enrolment**

01/01/2005

**Locations****Countries of recruitment**

England

Germany

Italy

United Kingdom

**Study participating centre**

**Institute of Neurology**  
London  
United Kingdom  
WC1N 3BG

## **Sponsor information**

### **Organisation**

AstraZeneca (UK)

### **Sponsor details**

Alderley Park  
Macclesfield  
United Kingdom  
SK10 2NA

### **Sponsor type**

Industry

### **ROR**

<https://ror.org/04r9x1a08>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

AstraZeneca (UK)

### **Alternative Name(s)**

AstraZeneca PLC, Pearl Therapeutics

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

For-profit companies (industry)

### **Location**

United Kingdom

# 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?
<a href="#">Results article</a>	Results	01/11/2006		Yes	No