

Intranasal zolmitriptan is effective and well tolerated in acute cluster headache

Submission date 14/02/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/02/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/08/2008	Condition category Signs and Symptoms	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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).

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Pain free at 30 minutes.

Completion date

01/01/2005

Eligibility**Key inclusion criteria**

Cluster headache with attacks longer than 45 minutes.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Germany

Italy

Study participating centre

Institute of Neurology

London

United Kingdom

WC1N 3BG

Sponsor information

Organisation

AstraZeneca (UK)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

AstraZeneca (UK)

Alternative Name(s)

AstraZeneca PLC, Pearl Therapeutics, AZ

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/11/2006		Yes	No