

A preference trial with rizatriptan 10 mg and ibuprofen 400 mg in migraine patients in the general practice

Submission date 16/05/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 16/05/2005	Overall study status Completed	☐ Protocol
Last Edited 04/03/2008	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr N.J. Wiendels

Contact details

Leiden University Medical Center
Department of Neurology, K5Q-106
P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 526 1730
N.J.Wiendels@lumc.nl

Additional identifiers

Protocol serial number

NTR33

Study information

Scientific Title

Study objectives

Patients prefer rizatriptan over ibuprofen for the acute treatment of migraine.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local Medical Ethics Committee.

Primary study design

Interventional

Study design

Randomised, double blind, double dummy, crossover study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Migraine

Interventions

Thirty-five triptan naive patients treat three attacks within each crossover period with either:

1. Rizatriptan 10 mg
2. Ibuprofen 400 mg

Preference is measured after the second period on a 10 cm scale.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Rizatriptan, ibuprofen

Primary outcome(s)

Direction and strength of patient preference on a 10 cm scale ranging from -5 (strong preference for treatment 1) to +5 (strong preference for treatment 2) where 0 indicates no preference.

Key secondary outcome(s)

1. Pain free rate at 2 hours postdose
2. Migraine disability assessment (MIDAS) score at visit 1

Completion date

09/11/2006

Eligibility

Key inclusion criteria

1. At least 18 years of age at visit 1
2. Current history of migraine with or without aura according to the International Headache Society (IHS) criteria
3. Experienced an average of at least one migraine attack per month for six months prior to entry to the study
4. Naïve to the use of 5HT1 agonists and ergotamine
5. Willing and able to understand and complete questionnaires
6. Willing and able to give informed consent prior to entry into the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. A history suggestive of ischaemic heart disease (IHD) (e.g. angina pectoris) or any atherosclerotic disease which places them at increased risk of coronary ischaemia
2. A history of cerebrovascular accident (CVA) or transient ischaemic attack (TIA)
3. A history of hypertension or a current blood pressure above 160/95 mmHg (measured three times)
4. A history of basilar, hemiplegic or ophthalmoplegic migraine
5. Impaired hepatic or renal function
6. A history of gastrointestinal disease
7. A history of asthma
8. Have a known or suspected hypersensitivity to, intolerance of, or contraindications to any component of the study medication
9. Currently use propranolol as a prophylactic agent
10. Currently use monoamine oxidase (MAO) inhibitors
11. Currently abuse alcohol, analgesics or psychotropic drugs
12. A history of hypertension
13. Any severe concurrent medical condition, which may affect the interpretation in a clinical trial
14. Females who are pregnant or breastfeeding, and females of childbearing potential who are not using a medically acceptable form of contraception
15. Have participated in a clinical trial within the previous month or are currently participating in any other clinical research study or clinical trial

Date of first enrolment

23/03/2005

Date of final enrolment

09/11/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Center

Leiden

Netherlands

2300 RC

Sponsor information

Organisation

Merck Sharp and Dohme BV (MSD) (The Netherlands)

ROR

<https://ror.org/05y28vr04>

Funder(s)

Funder type

Industry

Funder Name

Merck Sharp and Dohme BV (MSD) (The Netherlands)

Funder Name

Booth Healthcare International (The Netherlands) - now Reckittbenckiser

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration