

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

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| <b>Submission date</b><br>16/05/2005   | <b>Recruitment status</b><br>No longer recruiting    | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>16/05/2005 | <b>Overall study status</b><br>Completed             | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>04/03/2008       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input type="checkbox"/> Results                     |
|  |  | <input type="checkbox"/> Individual participant data |
|  |  | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# 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.

### Study design

Randomised, double blind, double dummy, crossover study

### 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

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 measure**

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.

### **Secondary outcome measures**

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

### **Overall study start date**

23/03/2005

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

35

### **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 ophtalmoplegic 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)

**Sponsor details**

P.O. Box 581

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Netherlands

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msdbvnl@merck.com

**Sponsor type**

Industry

**Website**

<http://www.msd.nl/>

**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****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