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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

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 propanolol 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
Haarlem
Netherlands
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+31 (0)23 515 3153
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