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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28934

Source
NTR

Brief title
N/A

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Painfree rate at 2 hours postdose;

2. MIDAS score at visit 1.

Study description

Background summary

Objective:

to compare patient preference between rizatriptan 10 mg and ibuprofen 400 mg. Methods: a randomised, double blind, double dummy, crossover study. Thirty-five triptan naieve patients treat 3 attacks within each crossover period. Preference is measured after the second period on a 10 cm scale, ankered by -5 (preference for treatment A) and +5 (preference for treatment B), 0 indicates no preference.

Study objective

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

Study design

N/A

Intervention

Our clinics were asked to treat three attacks with each medication and then fill out a preference trial (cross-over study).

Contacts

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Eligibility criteria

Inclusion criteria

1. The subject is at least 18 years of age at visit 1;

2. The subject has a current history of migraine with or without aura according to the IHS criteria;

3. The subject has experienced an average of at least one migraine attack per month for 6 months prior to entry to the study;

4. The subject is naïve to the use of 5HT1 agonists and ergotamine;

5. The subject is willing and able to understand and complete questionnaires;

6. The subject is willing and able to give informed consent prior to entry into the study.

Exclusion criteria

1. Subjects with 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. Subjects with a history of cerebrovascular accident (CVA) or transient ischaemic attack (TIA);

3. Subjects with a history of hypertension or a current blood pressure above 160/95 (measured 3 times);

4. Subjects with a history of basilar, hemiplegic or ophtalmoplegic migraine;

5. Subjects with impaired hepatic or renal function;

6. Subjects with a history of gastrointestinal disease;

7. Subjects with a history of asthma;

8. Subjects who have a known or suspected hypersensitivity to, intolerance of, or contraindications to any component of the study medication;

9. Subjects who currently use propanolol as a prophylactic agent;

10. Subjects who currently use MAO-inhibitors;

11. Subjects who currently abuse alcohol, analgesics or psychotropic drugs;

12. Subjects with a history of hypertension;

13. Subjects who have 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. Subjects who have participated in a clinical trial within the previous month or are currently participating in any other clinical research study or clinical trial.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-03-2005
Enrollment:	35
Type:	Actual

Ethics review

Positive opinion

Date:	06-12-2004
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9
NTR-old	NTR33
Other	: N/A
ISRCTN	ISRCTN18216584

Study results

Summary results
N/A