A preference trial with naratriptan 2,5 mg and paracetamol 1000 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-OMON22893

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. Changes in quality of life;

2. Pain free rate at 2 hours postdose.

Study description

Background summary

Traditional efficacy outcome measures in migraine trials are not sensitive enough to detect clinically relevant differences between two active agents. A promising novel method of comparing migraine treatments is a patient preference study, in which the patients are asked to use both treatments and then assign preference to one of the treatments. We would like to test the concept of patient preference as the primary endpoint in a randomised double blind cross-over study, comparing an analgesic with a triptan for the acute treatment of 3 migraine attacks in patients from the general population, who have not used a triptan or ergot before.

Objective:

to demonstrate patient preference for naratriptan 2.5 mg to paracetamol 1000 mg.

Design:

A randomised, double blind, double-dummy, cross-over study. Fourty subjects will be randomised to either naratriptan or paracetamol 1000 mg with a cross-over after 3 attacks. Subjects rate their satisfaction with treatment after each attack. Preference is evaluated after the second treatment period.

Study objective

Patients prefer naratriptan over paracetamol 1000 mg for the acute treatment of migraine attacks.

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 older than 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 day 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 ischemic 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 who currently abuse alcohol, analgesics or psychotropic drugs;

4. Subjects who have any severe concurrent medical condition which may affect the interpretation in a clinical trial;

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

6. Subjects with impaired hepatic or renal function;

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

8. Females who are pregnant or breastfeeding, and females of childbearing potential who are not using a medically acceptable form of contraception;

9. 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;

10. Subjects with a history of hypertension or a current bloodpressure above 160/95 (measured 3 times).

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):	01-01-2005
Enrollment:	40
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	NL13
NTR-old	NTR34
Other	: N/A
ISRCTN	ISRCTN57387771

Study results

Summary results
N/A