

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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28934

Bron

Nationaal Trial Register

Verkorte titel

N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 naive patients treat 3 attacks within each crossover period. Preference is measured after the second period on a 10 cm scale, anchored by -5 (preference for treatment A) and +5 (preference for treatment B), 0 indicates no preference.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 propranolol 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	23-03-2005
Aantal proefpersonen:	35
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	06-12-2004
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A