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

Gepubliceerd: 06-12-2004 Laatst bijgewerkt: 18-08-2022

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
NTR

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 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.

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

Publiek

Leiden University Medical Center (LUMC), Department of Neurology, K5Q-93,
P.O. Box 9600
N.J. Wiendels
Leiden 2300 RC
The Netherlands
+31 (0)71 5261730

Wetenschappelijk

Leiden University Medical Center (LUMC), Department of Neurology, K5Q-93,
P.O. Box 9600
N.J. Wiendels
Leiden 2300 RC
The Netherlands
+31 (0)71 5261730

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 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

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