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A preference trial with naratriptan 2.5 mg and paracetamol 1000 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
02/04/2008	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

NTR34

Study information

Scientific Title

Study objectives
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 three migraine attacks in patients from the general population, who have not used a triptan or ergot before.

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
A randomised, double blind, double-dummy, cross-over 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
1. Naratriptan 2.5 mg
2. Paracetamol 1000 mg

Subjects will be randomised to either naratriptan or paracetamol with a cross-over after three attacks. Subjects rate their satisfaction with treatment after each attack. Preference is evaluated after the second treatment period.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Naratriptan, paracetamol

Primary outcome measure
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 measures
1. Changes in quality of life
2. Pain free rate at 2 hours postdose

Overall study start date
01/01/2005

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. The subject is greater than or equal to 18 years of age at visit 1
2. The subject has a current history of migraine with or without aura according to the International Headache Society (IHS) criteria
3. The subject has experienced an average of at least one migraine day per month for six 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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
40

Key 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 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 contra-indications 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 blood pressure above 160/95 mmHg (measured three times)

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center (LUMC)
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (The Netherlands)

Sponsor details

Department of Neurology
Albinusdreef 2
P.O. Box 9600
Leiden
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Sponsor type
Hospital/treatment centre

Website
http://www.lumc.nl/english/start_english.html

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline (The Netherlands)

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Leiden University Medical Centre (LUMC) (The Netherlands)

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