ISRCTN73178636 https://doi.org/10.1186/ISRCTN73178636

Analgesic Drug Combinations in Neuropathic Pain (2004)

Submission date	Recruitment status	[X] Prospectively registered
31/08/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/08/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/10/2009	Nervous System Diseases	

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
MCT-69422

Study information

Scientific Title

Study objectives
The central hypothesis is that a combination of nortriptyline and gabapentin has a superior therapeutic profile than that of either drug alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This trial has been review and approved by the Queen's University Research Ethics Board.

Study design
Randomised controlled trial

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
Neuropathic pain

Interventions
Oral administration of:
1. Gabapentin
2. Nortriptyline
3. A gabapentin-nortriptyline combination

The end date of this trial is still being discussed, the anticipated end date entered above is an arbitrary date entered as one year after the trial started.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Gabapentin, nortriptylin

Primary outcome measure
The primary outcome measure of this study will be the mean daily pain intensity from the last seven days, at maximal tolerated dose, of each treatment period.

Secondary outcome measures
Secondary outcome measures will include frequency and severity of treatment-emergent adverse effects, global pain relief ratings, the short form McGill Pain Questionnaire, a pain interference questionnaire (Brief Pain Inventory), consumption of rescue medication (number of acetaminophen 325 mg tablets), a blinding questionnaire, two mood questionnaires (Beck Depression Inventory and Profile of Mood States) and a quality of life survey (SF-36).

Overall study start date
01/11/2004

Completion date
01/11/2005

Eligibility

Key inclusion criteria
1. Diabetic patients of either sex
2. 18 to 89 years of age
3. Distal, symmetric, sensory polyneuropathy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
71

Key exclusion criteria
1. Neuropathy attributable to an etiology other than diabetes (e.g. hypothyroidism, vitamin B12 deficiency, connective tissue disease, amyloidosis and toxic exposure)
2. Presence of a painful condition as severe as, but distinct from, their diabetic neuropathy pain
3. Pregnancy or lactation
4. End-stage kidney or liver disease
5. Moderate to severe heart disease (Myocardial Infarction [MI] within preceding year, unstable angina, cardiac conduction defect or congestive heart failure)

6. Cardiovascular autonomic neuropathy
7. Postural hypotension more than 20 mmHg on initial assessment
8. Baseline mild to severe sedation or ataxia due to required concomitant drugs, or any other cause
9. Males with urinary symptoms attributable to benign prostatic hypertrophy
10. Presence of a seizure disorder
11. Angle-closure glaucoma
12. Ongoing administration of Monoamine Oxidase (MAO) inhibitors and/or a serious psychiatric disorder as diagnosed by a psychiatrist
13. Ongoing administration of anticonvulsants which induce cytochrome P450 enzymes (e.g. carbamazepine, oxcarbazepine)
14. Hypersensitivity to any of the study medications
15. History of significant abuse of illicit drugs, prescription drugs or alcohol
16. Lack of a primary physician
17. Patients who live alone and cannot assure daily contact with a friend, family member or caregiver

Date of first enrolment
01/11/2004

Date of final enrolment
01/11/2005

Locations

Countries of recruitment
Canada

Study participating centre
Queen's University
Kingston, ON
Canada
K7L 2V7

Sponsor information

Organisation
Canadian Institutes of Health Research (CIHR) (Canada)

Sponsor details
Room 97
160 Elgin Street
Address locator: 4809A
Ottawa, Ontario
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info@cihr-irsc.gc.ca

Sponsor type
Research organisation

Website
http://www.cihr-irsc.gc.ca

ROR
https://ror.org/01gavpb45

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-69422)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/10/2009		Yes	No