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Nutmeg extracts for painful diabetic neuropathy

Submission date	Recruitment status	[X] Prospectively registered
21/07/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/08/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/08/2011	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
nutmeg1234

Study information

Scientific Title
Nutmeg extracts for painful diabetic neuropathy: a randomised controlled trial

Acronym
NUTPADIN

Study objectives
Can nutmeg extracts reduce pain and/or improve quality of life in patients with painful diabetic neuropathy?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Faculty Medical Sciences, University of the West Indies, Trinidad, approved on the 6th July 2009

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Can be found at http://nutpadin.webs.com/patientinformation.htm

Health condition(s) or problem(s) studied
Painful diabetic neuropathy

Interventions
A random number generating software will be used to generate two equal sets (32 per set) of random numbers ranging from 1 - 64. Consecutive eligible patients will pick one envelope each containing one number ranging from 1 - 64. All envelopes will be sealed without any external marking and will be drawn blindly from an opaque bag. Patients in set one will be assigned to the intervention and patients in the other set will be given placebo.

Before the intervention a washout period of one week for use of any topical medications in the area of PDN (painful diabetic neuropathy) symptoms will be advised. The baseline outcome measure will be determined after the washout period by a blinded assessor. An independent person not involved in the allocation process will be responsible for distribution of the treatments and placebos. He will advise the patient to apply the formulation only to the affected areas for PDN symptoms. Participants will be instructed to apply four sprays, 3 times a day, followed by gentle massage. This will be done for four weeks. The intervention will be a

commercially available topical preparation containing: mace oil (2%) and nutmeg oil (14%), methyl salicylate (6%), menthol (6%), coconut oil and alcohol. The placebo will be a topical preparation containing: methyl salicylate (6%), menthol (6%), coconut oil and alcohol.

Both treatments will be in similar containers bearing numbers (1 - 64) linked to the pre-randomised sequence in the envelopes. They will bear no trademarks or descriptions identifying their main ingredients or composition. With the exception of any prior topical medications used in the area of PDN symptoms, participants will be instructed to remain compliant with all other ongoing therapies (e.g., insulin, oral hypoglycaemics, tricyclic antidepressants, etc). Patients will be followed up for a duration of 4 weeks.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Nutmeg extracts

Primary outcome measure
Pain, measured using the Brief Pain Inventory for Diabetic Painful Neuropathy (BPI-DPN) and The Neuropathic Pain Symptom Inventory (NPSI) at baseline and at one, two and four weeks.

Secondary outcome measures
Quality of life, measured using the Brief Pain Inventory for Diabetic Painful Neuropathy (BPI-DPN) at baseline and at one, two and four weeks.

Overall study start date
01/09/2009

Completion date
30/10/2009

Eligibility

Key inclusion criteria
1. Aged 21 years and older, either sex
2. Diabetes or impaired glucose tolerance
3. Neuropathic pains score greater than or equal to 4 as determined by the 4-item Neuropathic Pain (DN4) Questionnaire
4. Symptoms limited to the limbs

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
64

Key exclusion criteria
1. Other confirmed aetiologies of pain in extremities, e.g., soft tissue injuries/infections, tendinitis, spurs
2. Broken skin near pain sites or active skin rash
3. Known salicylate allergy

Date of first enrolment
01/09/2009

Date of final enrolment
30/10/2009

Locations

Countries of recruitment
Trinidad and Tobago

Study participating centre
1 Cedar Avenue
Valsayn North
Trinidad and Tobago
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Sponsor information

Organisation
University of West Indies (Trinidad)

Sponsor details
St Augustine Campus
St Augustine
Trinidad and Tobago
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Sponsor type
University/education

Website
http://sta.uwi.edu/

ROR
https://ror.org/003kgv736

Funder(s)

Funder type
University/education

Funder Name
University of West Indies (Trinidad) - St Augustine Campus

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