

Nutmeg extracts for painful diabetic neuropathy

Submission date 21/07/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 05/08/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/08/2011	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Shastri Motilal

Contact details

1 Cedar Avenue
Valsayn North
Trinidad and Tobago
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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