

The Capsaicin 8% patch for pain relief in diabetic peripheral neuropathy

Submission date 24/08/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/09/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 11/10/2023	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The current treatments for painful diabetic peripheral neuropathy (nerve damage caused by diabetes) have limited efficacy, and many significant side effects. There are no approved treatments to prevent or modify the progression of nerve damage. However, the capsaicin 8% patch, a skin plaster, is a new effective, safe and well-tolerated treatment for painful diabetic peripheral neuropathy. When used for 30 minutes as a single application, it can provide pain relief for 3 months and longer. This study aims to look at whether repeated applications of the capsaicin 8% patch can not only reduce pain but also prevent or modify the underlying nerve damage.

Who can participate in this study?

Patients who have had painful diabetic peripheral neuropathy for at least 1 year and have an average daily pain score of $\geq 4/10$ on the Numerical Pain Rating scale

What does the study involve?

Patients will be randomly allocated to one of two groups - either the intervention group or the control group. Both groups will receive their usual treatment; however, the intervention group will also receive Capsaicin 8% patch treatment for 30 minutes every 12 weeks over a 12 month period. Patients in both groups will receive various tests at 12 week intervals, including skin biopsies.

What are the possible benefits and risks of participating?

The possible benefits of participating in this study may include a reduction in pain and other sensory symptoms. There are no known risks to participants taking part in this study.

Where is the study run from?

Hammersmith Hospital, London (UK)

When is the study starting and how long is it expected to run for?

January 2018 to November 2021

Who is funding the study?
Diabetes UK (UK)

Who is the main contact?
Professor Praveen Anand
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Contact information

Type(s)
Scientific

Contact name
Prof Praveen Anand

Contact details
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Additional identifiers

Clinical Trials Information System (CTIS)
2017-004746-17

Protocol serial number
17HH4283

Study information

Scientific Title
Pain relief with disease modification by Capsaicin 8% patch: a clinical study in diabetic peripheral neuropathy.

Acronym
Capsaicin pain patch.

Study objectives
The aim of this study is to investigate whether repeated treatments with the capsaicin 8% patch reduce the nerve pain and help the damaged nerve fibres to regrow normally.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridgeshire and Hertfordshire Research Ethics Committee, 02/01/2018,
REC reference number: 17/EE/0498

Study design

Interventional longitudinal randomised parallel trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetic peripheral neuropathy

Interventions

Eligible patients will be randomised 2:1 to receive either the Capsaicin 8% patch and the usual Standard Of Care (SOC) (intervention group) or SOC alone (control group). Randomisation for the 2 groups will be via the hospital pharmacy. Patients in the intervention group will receive applications of Capsaicin 8% patch for 30 minutes to the feet at each visit. Visits will be every 12 weeks for a 12 month period, as licensed. Patients in the control group will continue to take their usual medication, as part of their standard of care. Patients in both groups will be assessed with bedside sensory tests and skin biopsy at 3, 6, 9 and 12 months.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Capsaicin 8% patch (Qutenza 179 mg cutaneous patch)

Primary outcome(s)

Reduction in pain, assessed using the Visual Analogue Scale (VAS) at the baseline and at the end of the study

Key secondary outcome(s)

Changes in description of quality and nature of pain, assessed at the baseline and the end of the study using the following:

1. Modified version of the Short-form McGill Pain Questionnaire 2 (SF-MPQ-2)
2. Patient Global Impression of Change (PGIC)
3. Change in area of pain or numbness, assessed using bedside sensory tests

Completion date

11/11/2021

Eligibility

Key inclusion criteria

1. Painful distal, symmetrical, sensorimotor polyneuropathy due to diabetes of at least 1 year duration
2. Average daily pain score of $\geq 4/10$ for painful diabetic neuropathy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

50

Key exclusion criteria

1. Other painful medical conditions
2. Significant renal impairment
3. Heart failure

Date of first enrolment

02/08/2018

Date of final enrolment

07/04/2021

Locations**Countries of recruitment**

United Kingdom

Study participating centre**Hammersmith Hospital**

Peripheral Neuropathy Unit, Imperial College London, Hammersmith Hospital,
Du Cane Rd
London
United Kingdom
W12 ONN

Sponsor information**Organisation**

Imperial College London

ROR

Funder(s)

Funder type

Not defined

Funder Name

Diabetes UK

Results and Publications

Individual participant data (IPD) sharing plan

Pseudonymised data will be stored within the department on a secure University computer in accordance with Imperial College policy. Only researchers involved in the study will have access to these data. During the overall duration of the study medical records and the data collected for the study may also be looked at by authorised people from the Sponsor or NHS Trust, to check that the study is being carried out correctly. All will have a duty of confidentiality to the research participant and will do their best to meet this duty. By signing the consent form, patients authorise the release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/10/2022	11/10/2023	Yes	No
HRA research summary			28/06/2023	No	No