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

Submission date
24/08/2018

Recruitment status
No longer recruiting

Registration date
14/09/2018

Overall study status
Completed

Last Edited
11/10/2023

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 ≥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
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Additional identifiers

EudraCT/CTIS number
2017-004746-17

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

Secondary outcome measures
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

Overall study start date
01/01/2018

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 ≥4/10 for painful diabetic neuropathy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

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
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W12 ONN

Sponsor information

Organisation
Imperial College London

Sponsor details
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Sponsor type
University/education

Website
https://www.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Not defined

Funder Name
Diabetes UK

Results and Publications

Publication and dissemination plan
We aim to report and disseminate the results of the study in peer reviewed scientific journals and conference presentation.

Intention to publish date
01/12/2022

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?
HRA research summary			28/06/2023	No	No
Results article		26/10/2022	11/10/2023	Yes	No