ISRCTN12494732 https://doi.org/10.1186/ISRCTN12494732

# Understanding the risk factors for neuropathic (nerve) pain in adults with diabetes and/or who have received neurotoxic chemotherapy to treat cancer

**Submission date**
07/11/2022

**Recruitment status**
No longer recruiting

**Registration date**
11/11/2022

**Overall study status**
Completed

**Last Edited**
15/07/2026

**Condition category**
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Neuropathic pain is caused by direct damage to the nerves. Not everyone with a disease or trauma which can cause neuropathic pain goes on to develop neuropathic pain. People who do develop neuropathic pain have a wide range of severities and outcomes. This difference in onset, severity and outcome is due to a complex interaction between genetic and environmental factors. The exact contribution and interaction of these factors is currently unknown but is vital to understand to inform treatment and prevention.
PAINSTORM is a group of research centres from the UK and Belgium. Our aim is to understand the disease processes of neuropathic pain. We also want to use this knowledge to improve the outcome for people with neuropathic pain. Our research follows on from the successful DOLORisk study, which identified factors linked with the presence, onset and outcome of neuropathic pain in the general population. We need to confirm these findings in specific populations and we will follow these people up for longer.
Dundee will lead a part of PAINSTORM (PAINSTORM Dundee Epidemiology) that aims to test the findings from DOLORisk and seek other previously unidentified associations with neuropathic pain. We will focus on two conditions that have a high risk of developing neuropathic pain – diabetes and chemotherapy treatment.

Who can participate?
Adults 18 years or older, who are on the GoDARTS register and took part in both DOLORisk Dundee questionnaires, or on the SHARE register and have diabetes mellitus and/or who have received neurotoxic chemotherapy for the treatment of cancer.

What does the study involve?
Potential participants will be invited to complete a questionnaire collecting data on any pain they may currently have, as well as important demographic, lifestyle and health related information. Participants from SHARE will complete a follow-up questionnaire, approximately 18 months after baseline.

What are the possible benefits and risks of participating?
Our study might not bring any direct benefits to participants, but we hope that the information from this large research project will improve the treatment of people receiving chemotherapy for cancer and people with diabetes and help to develop new ways to prevent or treat neuropathic pain. We do not think there will be any risks in taking part as participants will only complete a maximum of two questionnaires at home.

Where is the study run from?
University of Dundee (UK)

When is the study starting and how long is it expected to run for?
July 2021 to July 2026

Who is funding the study?
1. UK Research and Innovation
2. Versus Arthritis (UK)
3. Eli Lilly and Company (USA)

Who is the main contact?
Dr Harry Hebert, h.hebert@dundee.ac.uk - Principal Investigator
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# Contact information

### Type(s)
Scientific, Principal investigator, Public

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Public, Scientific

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# Additional identifiers

### Integrated Research Application System (IRAS)
304842

### Central Portfolio Management System (CPMS)
53774

### Protocol serial number
2-015-22

# Study information

### Scientific Title
Partnership for Assessment and Investigation of Neuropathic Pain: Studies Tracking Outcomes, Risks and Mechanisms: Dundee Epidemiology study - investigating risk factors and possible causes of neuropathic pain

### Acronym
PAINSTORM Dundee Epidemiology

### Study objectives
In the presence of diabetes and/or potentially neurotoxic chemotherapy, an individual's risk of developing neuropathic pain and its complications can be predicted by specific psychosocial, genetic and clinical risk factors.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 26/07/2022, London - Brighton & Sussex Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 1048202/41; brightonandsussex.rec@hra.nhs.uk), ref: 22/PR/0803

### Primary study design
Observational

### Study design
Single-centre prospective cohort study

### Study type(s)

Other

## Health condition(s) or problem(s) studied
Neuropathic pain in adults with diabetes and/or who have received potentially neurotoxic chemotherapy to treat cancer.

## Interventions
This study aims to identify and replicate genetic and environmental risk factors for developing neuropathic pain in adults with diabetes and/or who have received potentially neurotoxic chemotherapy to treat cancer, and predict its outcomes (remission or exacerbation). The identification of neuropathic pain and pain-related traits and comorbidities will mainly be achieved through longitudinal survey-based questionnaires of three cohorts, UK Biobank (general population, Great Britain), GoDARTS (diabetes, mainly Type 2, from Tayside, Scotland) and SHARE (general population, Scotland).

## Intervention Type
Other

## Primary outcome(s)
1. Presence of neuropathic pain at baseline, 18 and 72 months, assessed using survey-based questionnaires including:
1.1. Chronic pain identification questionnaire (presence of pain, currently taking pain medication and duration)
1.2. Douleur Neuropathique en 4 questions [DN4] questionnaire
1.3. List of body sites
1.4. Michigan Neuropathy Screening Instrument [MNSI] (only those with diabetes)
1.5. European Organisation for Research and Treatment of Cancer - Chemotherapy-Induced
1.6. Peripheral Neuropathy 20-item questionnaire [EORTC-CIPN20] (only those who have received neurotoxic chemotherapy)

## Key secondary outcome(s)
At baseline, 18 and 72 months, assessed using survey-based questionnaires:
1. Severity of pain:
1.1. Chronic Pain Grade (CPG) questionnaire
1.2. Brief Pain Inventory (average)
2. Quality of life:
2.1. EQ5D-5L questionnaire
3. Psychological health:
3.1. PROMIS Depression Score
3.2. PROMIS Anxiety Score
3.3. PROMIS Sleep Score
3.4. PROMIS Support
3.5. TIPI Personality questionnaire
3.6. Pain Catastrophising scale
3.7. Traumatic Experiences
4. Lifestyle:
4.1. Smoking questionnaire
4.2. Alcohol questionnaire
4.3. Saltin-Grimby Physical Activity Level Scale (SGPALS)
5. Demographics:
5.1. Age (years)

5.2. Gender
5.3. Ethnicity
5.4. Social Deprivation (SIMD)
5.5. Weight (kg)
5.6. Height (cm)
5.7. Years in full-time education
5.8. Working status
5.9. Household income
6. Clinical:
6.1. Diabetes/Chemotherapy Duration
6.2. Diabetes Type

### Completion date
14/07/2026

## Eligibility

### Key inclusion criteria
1. 18 years or older
2. Existing consent to be re-contacted.
3. Identified as being currently alive.
4. Currently has a phone number, email or postal address on file
5. AND EITHER:
5.1. Adults on the SHARE register with diabetes mellitus AND/OR who have received potentially neurotoxic chemotherapy for the treatment of cancer, OR
5.2. Adults on the GoDARTS register who responded to two questionnaires for the DOLORisk Dundee study (REC reference: 15/YH/0285).

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 Years

### Upper age limit
120 Years

### Sex
All

### Total final enrolment
2469

### Key exclusion criteria

Does not meet inclusion criteria

**Date of first enrolment**
27/03/2023

**Date of final enrolment**
31/12/2025

# Locations

**Countries of recruitment**
United Kingdom

Scotland

**Study participating centre**
**University of Dundee**
Perth Road
Dundee
Scotland
DD1 4HN

# Sponsor information

**Organisation**
University of Dundee

**ROR**
https://ror.org/03h2bxq36

# Funder(s)

**Funder type**
Government

**Funder Name**
UK Research and Innovation

**Alternative Name(s)**
UKRI

**Funding Body Type**

Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

**Funder Name**
Versus Arthritis

**Alternative Name(s)**
Arthritis UK

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
United Kingdom

**Funder Name**
Eli Lilly and Company

**Alternative Name(s)**
Lilly, Eli Lilly & Company, Eli Lilly & Co., Eli Lilly And Co, Eli Lilly & Co

**Funding Body Type**
Government organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
United States of America

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (Alleviate Pain Data Hub/https://www.hdruk.ac.uk/helping-with-health-data/health-data-research-hubs/alleviate/).

Pseudonymised, individual-level data will be stored in the Alleviate Data Hub once the study is complete. Details on requesting access will be made available at the Alleviate website (https://alleviate.ac.uk/). Specific consent will not be obtained, but participants have been informed that we may share their study information with other researchers, after personal identifiers have been removed.

## IPD sharing plan summary

Stored in non-publicly available repository

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Full version version 1 | 23/05/2022 | 09/11/2022 | No | Yes |
| Participant information sheet | Pocket version version 1 | 23/05/2022 | 09/11/2022 | No | Yes |
| Participant information sheet | | | 02/06/2023 | No | Yes |
| Participant information sheet | | | 02/06/2023 | No | Yes |
| Protocol file | version 1 | 23/05/2022 | 09/11/2022 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |