

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

<b>Submission date</b> 07/11/2022	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/11/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/12/2024	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Professor Blair H. Smith; b.h.smith@dundee.ac.uk - Principal Investigator

Dr Harry Hebert, h.hebert@dundee.ac.uk - Study Coordinator

## Contact information

### Type(s)

Principal investigator

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

304842

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

2-015-22, IRAS 304842, CPMS 53774

**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**

### **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

### **Study design**

Single-centre prospective cohort study

### **Primary study design**

Observational

### **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**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

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## 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Full version version 1	23/05/2022	09/11/2022	No	Yes
<a href="#">Participant information sheet</a>	Pocket version version 1	23/05/2022	09/11/2022	No	Yes
<a href="#">Participant information sheet</a>			02/06/2023	No	Yes
<a href="#">Participant information sheet</a>			02/06/2023	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet version 1	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version 1	23/05/2022	09/11/2022	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes