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 Recruiting	[X] Prospectively registered[X] ProtocolStatistical analysis plan		
Registration date	Overall study status Ongoing Condition category Nervous System Diseases			
11/11/2022		Results		
Last Edited		Individual participant data		
19/12/2024		[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?
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

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

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 Dundee United Kingdom 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)

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 HRA research summary	Details	Date created	Date added 28/06/2023	Peer reviewed? No	Patient-facing? 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	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