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
Recruiting

Registration date
11/11/2022

Overall study status
Ongoing

Last Edited
19/12/2024

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?
Professor Blair H. Smith; b.h.smith@dundee.ac.uk - Principal Investigator
Dr Harry Hebert, h.hebert@dundee.ac.uk - Study Coordinator

Study website
https://www.dundee.ac.uk/projects/painstorm-dundee-epidemiology

Contact information

Type(s)
Principal Investigator

Contact name
Prof Blair Smith

ORCID ID
http://orcid.org/0000-0002-5362-9430

Contact details
Division of Population Health and Genomics
Ninewells Hospital and Medical School
University of Dundee
Dundee
United Kingdom
DD2 1UB
+44 1382383795
b.h.smith@dundee.ac.uk

Type(s)
Scientific

Contact name

Dr Harry Hebert

ORCID ID
http://orcid.org/0000-0003-1753-6592

Contact details
Division of Population Health and Genomics
Ninewells Hospital and Medical School
University of Dundee
Dundee
United Kingdom
DD2 1UB
+44 1382383191
h.hebert@dundee.ac.uk

Type(s)
Public

Contact name
Dr Harry Hebert

Contact details
Division of Population Health and Genomics
Ninewells Hospital and Medical School
University of Dundee
Dundee
United Kingdom
DD2 1UB
+44 1382383191
h.hebert@dundee.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
304842

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
See study ouputs table

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 measure
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)

Secondary outcome measures
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

Overall study start date
01/07/2021

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Biobank - 167,000; SHARE - 7,000; GoDARTS - 500

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
Scotland

United Kingdom

Study participating centre

University of Dundee
Perth Road
Dundee
United Kingdom
DD1 4HN

Sponsor information

Organisation
University of Dundee

Sponsor details
TASC
Level 3 Residency block
Ninewells Hospital
Dundee
Scotland
United Kingdom
DD1 9SY
+44 1382383297
TASCgovernance@dundee.ac.uk

Sponsor type
University/education

Website
http://www.dundee.ac.uk/tasc

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

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
There will be a clear PAINSTORM strategy for reporting and dissemination of scientific output, overseen by a dissemination committee. Patient partners will be active members of the dissemination committee. Patient partners will lead the identification of ways of disseminating the results and review outputs aimed at patients and public. Results will be written up in high impact open access scientific papers and presented at scientific conferences internationally. A PAINSTORM website will be created, with public access, and papers will be shared there. Where

results potentially affect patient care, e.g. through the identification of stratified approaches to risk management, these will be shared with stakeholders such as patient groups, national regulatory and professional bodies, health professionals and the general public, with a view of maximising overall impact. A Final Report will be prepared for the funding body and for the Ethics Committee.

Intention to publish date
31/12/2026

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?
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
Protocol file	version 1	23/05/2022	09/11/2022	No	No
Participant information sheet			02/06/2023	No	Yes
Participant information sheet			02/06/2023	No	Yes
HRA research summary			28/06/2023	No	No