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Pain and sensory function in childhood cancer survivors

Submission date
01/04/2025

Recruitment status
Recruiting

Registration date
16/04/2025

Overall study status
Ongoing

Last Edited
10/04/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
New treatments have greatly improved survival for critically ill children with cancer. Understanding the long-term effects of cancer and cancer treatment on general health and well-being is extremely important research for young people with cancer in the UK.

Pain affects well-being and we know some cancer survivors have ongoing pain years later. At Great Ormond Street Hospital, children and young people who finished treatment for leukaemia or lymphoma have regular health checks at our Haematology/Oncology Late Effects Clinic. In a previous study, we asked 48 young people at this clinic about their pain. One in 5 had pain they felt was due to their previous cancer or its treatment. This could be due to chemotherapy producing long-term changes in nerves and nerve-injury pain in the hands and feet. This pain is often difficult to treat. However, many more (over half) had pain in one or more parts of the body, including the back, limbs, abdomen or head. We now want to find out more about the types of pain these young people are experiencing, and how it is affecting their lives.

Who can participate?
Young people aged 14-18 years attending the Late Effects Clinic will be asked to join our study. Before their appointment the young person and their family will receive written information about the study. They can then freely decline or choose to meet the researchers to talk about the study. If they wish to take part, one assessment taking 90-120 minutes can be arranged at a time that suits them.

What does the study involve?
We will ask young people to:
• tell us about their pain: where is it, how strong is it, what it feels like and what makes it better or worse.
• complete screening questionnaires to find nerve-injury and nerve pain.
• have specialised tests to measure touch, temperature and pressure sensitivity (known as quantitative sensory testing) on the hand, foot and near other current pain. Different patterns of sensitivity help us understand more about what is causing the pain.
• fill in questionnaires that have been developed for young people to tell us about their quality of life, mood, how they manage pain, what activities they do, and if they have disturbed sleep or

feel tired.
• do tests that measure thinking skills on an iPad, as pain, poor sleep and previous cancer treatments can make thinking clearly more difficult.

What are the possible benefits and risks of participating?
This study has been designed with patient and parent partners to check it is relevant to them and the testing does not take too long.
We will share our findings about pain and its effects on well-being with professionals who look after young people with cancer, and with patients and families via our patient advisory group and cancer care networks.

We want to find which tests and questionnaires are best at finding problems, and see if these can become part of usual care for all young cancer survivors. This will ensure problems are picked up as early as possible. Understanding the types of pain will help us direct young people to the best therapies to improve pain and well-being.

Risks to participants are minor. The current study co-ordinators have used the same tests and questionnaires in previous research studies with young people.

All participating young people will have ongoing care with the Haematology/BMT Late Effects Multidisciplinary Team. We will let young people and families know that if any test results suggest problems, we will check with them and ask to share this information with their clinical team.

Where is the study run from?
The study will be run from Great Ormond Street Hospital and the UCL GOS Institute of Child Health in London (UK)

When is the study starting and how long will it run for?
We started planning the current study in 2023. This is a follow-up to a previous study that ran from 2018-2020 but was interrupted by the COVID pandemic. Recruitment will start in April 2025 and the study will run for 3 years.

Who is funding the study?
A research grant was awarded by the Medical Research Foundation, UK.

Who is the main contact?
Prof Suellen Walker (Principal Investigator), suellen.walker@ucl.ac.uk
Dr Natasa Ganea (Research Fellow), n.ganea@ucl.ac.uk
Dr Vesna Pavasovic (Late Effects Specialist)

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
241655

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
18NC01

Study information

Scientific Title
Pain experience and somatosensory function in survivors of paediatric haematological malignancies: A cross-sectional cohort study in late adolescence

Study objectives
Primary Hypothesis:
Childhood haematological malignancy and/or its treatment is associated with long-term changes in somatosensory function, which can be detected at 14-18 years of age.

Secondary Hypotheses:
1. Self-reported outcomes relating to current pain, quality of life, anxiety, pain catastrophizing and resilience in young people with previous haematological malignancy during childhood will differ from published measures in healthy age-matched groups.
2. The Self-report Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) screening tool has clinical utility for recognition of neuropathic pain, and the Ped-mTNS will identify symptoms and signs of persistent neuropathy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/09/2024, London - Hampstead Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048234; nrescommittee.london-hampstead@nhs.net), ref: 18/LO/0533

Study design
Cross-sectional observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request participant and/or parent information sheets.

Health condition(s) or problem(s) studied
Pain and somatosensory function in survivors of paediatric haematological malignancies

Interventions
This single-centre cross-sectional observational cohort study will be carried out with adolescents and young people (aged 14-18 years) recruited from the Paediatric Haematology/Bone Marrow Transplant Late Effects Clinic at the Great Ormond Street Hospital NHS Foundation Trust. All testing will be carried out in the Sensory Testing Room, Level 1 Morgan Stanley Clinical Building, Great Ormond Street Hospital. Testing will only be carried out following informed written consent or assent in young people aged 14-18 years, plus parental consent for participants under 16 years of age or as required. Participants will undergo one episode of assessment which

will encompass i) questionnaires, ii) neuropathic pain and neuropathy screening tools; iii) quantitative sensory testing; and iv) cognitive testing. This will be scheduled at a time chosen by the family and will take up to 2 hours with a refreshment break. Reimbursement for travle costs is available.

Intervention Type
Other

Primary outcome measure
Alterations in somatosensory function measured at a single time point:
1. Neuropathy is measured using Pediatric-modified Total Neuropathy Scale
2. Thermal detection thresholds are measured using Senselab MSA Thermal Stimulator
3. Mechanical detection threshold is measured using von Frey monofilaments
4. Vibration detection threshold is measured using Rydel-Seiffer graded tuning fork
5. Mechanical pinprick threshold is measured using weighted pinprick stimulators
6. Pressure pain threshold is measured using Somedic SENSEBox algometer
7. Wind-up ratio is measured using weighted pinprick stimulator
8. Dynamic brush allodynia is measured using calibrated brush
9. Thermal hyperalgesia is measured using Somedic RollTemp
10. Mechanical sensitivity is measured using von Frey hairs
11. Brush allodynia is measured using calibrated brush
12. Pain sensitivity and/or tolerance is measured using Cold Pressor Test

Secondary outcome measures
Prevalence and type of chronic pain:
1. Pain history is measured using Case Report Form
2. Intensity of current pain is measured using Visual Analog Scales
3. Average pain over the last week is measured using Visual Analog Scales
4. Worst pain over the last week is measured using Visual Analog Scales

Self-reported outcome measures:
5. Presence and frequency of different sensory and affective pain descriptors are measured using McGill questionnaire
6. Quality of life is measured using Paediatric Quality of Life Inventory
7. Anxiety is measured using State and Trait Anxiety Inventory
8. Pain catastrophizing is measured using Pain Catastrophizing Scale
9. Resilience is measured using Connor-Davidson Resilience Scale
10. Neuropathic pain is measured using Self-Report Leeds Assessment of Neuropathic Symptoms and Signs

Overall study start date
01/08/2023

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Young people aged 14-18 years with a prior diagnosis and treatment of paediatric haematology malignancies attending the Great Ormond Street Hospital Haematology/BMT Late Effects clinic

Participant type(s)
Patient

Age group
Child

Lower age limit
14 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
72

Key exclusion criteria
Young people with significantly impaired comprehension (less than school level for 10 year old) or inadequate English language skills for sensory testing instructions.
Patients with chronic Graft vs. Host Disease (GVHD) will be excluded as multiple comorbidities would increase heterogeneity of the sample.

Date of first enrolment
15/04/2025

Date of final enrolment
31/10/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Great Ormond Street Hospital for Children
Great Ormond Street
London
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WC1N 3JH

Study participating centre

UCL Great Ormond Street Institute of Child Health
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Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.gosh.nhs.uk/

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Charity

Funder Name
Medical Research Foundation

Results and Publications

Publication and dissemination plan
1. Publication in peer-reviewed journals
2. Presentation and workshops at Continuing Medical Education meetings, including cancer care

networks (eg. PanCare European Late Effects Collaborative Group)
3. Parent and Patient/Young People Focus Groups: co-design pamphlets and media for communication with young people and families.

Intention to publish date
31/10/2028

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication