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Looking for nerve problems caused by chemotherapy: determining the effectiveness of an early identification screening programme

Submission date
16/01/2026

Recruitment status
Recruiting

Registration date
26/05/2026

Overall study status
Ongoing

Last Edited
26/05/2026

Condition category
Nervous System Diseases

[ ] 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
Children receiving chemotherapy may develop chemotherapy-induced peripheral neuropathy (CIPN) during their treatment. CIPN is defined as any injury, inflammation or degeneration of peripheral nerves due to chemotherapy. Peripheral nerves are those nerves outside the brain and spinal cord, e.g., those in the arms and legs. Signs and symptoms of CIPN include pain, muscle weakness, sensory problems (e.g., pins and needles) and autonomic involvement (e.g. constipation). Progressive weakness and pain can lead to walking and balance problems. There are currently no guidelines or evidence on how best to identify CIPN, and it is unknown if early therapy intervention can help longer-term outcomes.

This study aims to find out how feasible it is to carry out a study that tests the impact of a screening programme for CIPN on children's long-term physical outcomes.

Who can participate?
Newly diagnosed children aged 4-<18 years who are at high risk of CIPN.

What does the study involve?
The researchers want to find out whether spotting nerve problems early through screening can help improve outcomes for children, such as reducing pain or helping them walk more easily. Before doing a large study, they first need to check that all parts of the research are practical and acceptable to both children and their parents. To do this, they will run a smallscale version of the study to see what works well and what may need to be changed. This study will compare the usual care children receive with a screening programme designed to detect chemotherapyrelated nerve problems at an earlier stage.

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration

Where is the study run from?
Alder Hey Childrens NHS Foundation Trust, UK.

When is the study starting and how long is it expected to run for?
August 2023 to June 2026.

Who is funding the study?
1. Charitable Funding at Alder Hey Children's NHS Foundation Trust, UK.
2. Isle of Man Anti-Cancer Association, Isle of Man.

Who is the main contact?
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Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
317770

Study information

Scientific Title
Screening for chemotherapy induced peripheral neuropathy: determining the effectiveness of an early identification screening programme

Acronym
SCIP

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 19/05/2023, North West - Liverpool Central Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 2071048008; liverpoolcentral.rec@hra.nhs.uk), ref: 23/NW/0094

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Screening

Study type(s)

Health condition(s) or problem(s) studied
Chemotherapy induced peripheral neuropathy

Interventions
Randomisation;
Following informed consent and after assessment 1, children will be randomised into two groups: usual care versus screening programme (using sealedenvelope.com ensuring allocation concealment).

1. Intervention Group (Screening plus usual care)
• Children allocated to the screening group will be screened using the Ped-m TNS (a validated CIPN assessment for children with ALL/non-CNS solid tumours) as follows: S1 at diagnosis, S2 4 weeks, S3 8 weeks, S4 12 weeks, S5 16 weeks and S6 at 24 weeks post diagnosis (screening time points informed by vincristine schedule).
• The Edinburgh Visual Gait Score will be undertaken at S1 and S4.
• The Oxford foot and ankle questionnaire will be undertaken at S2, 3, 5 and S6.
• If a child is identified with CIPN (Ped-m TNS >4), they will access routinely available input, which may include dose modification, referral to therapies and analgesia. Any intervention will be documented.
• Physiotherapy approach will be standardised using the Stoplight Programme, to ensure the same criteria/intensity of intervention between the two groups.

2. Usual Care
• Usual care group children will continue with their oncology treatment as per routine treatment. If any concerns are raised regarding CIPN by the child/parents/clinicians during routine hospital visits, they will access routinely available input (same as detailed for the screening group). This

will be recorded.
• If the child is referred to physiotherapy, the initial assessment will include the Ped-m TNS documenting the severity of CIPN on referral to physiotherapy.
• If a child is identified with CIPN (Ped-m TNS >4), they will access routinely available input, which may include dose modification, referral to therapies and analgesia. Any intervention will be documented.
• Physiotherapy approach will be standardised using the Stoplight Programme, to ensure the same criteria/intensity of intervention between the two groups.

3. Study assessments
Both groups of children will be assessed at A1 at diagnosis, and A2 6 months and A3 12 months post diagnosis using 8 outcome measures (BOT-II, Oxford questionnaire, TUG, 10MWT, Lansky Play Performance Scale, 9HPT, ankle ROM and dorsiflexion muscle strength), further details below.
Assessment Schedule for SCIP study

Assessment (A) Intervention Group Usual Care
A1 At time of recruitment (within 1 week of diagnosis) At time of recruitment (within 1 week of diagnosis)
A2 6 months post diagnosis 6 months post diagnosis
A3 12 months post diagnosis 12 months post diagnosis

Intervention Type
Other

Primary outcome(s)
1. Process measures of feasibility measured using study data on: 1. The number of children who are identified; 2. The number of children who are recruited (and barriers to recruitment); 3. Willingness to be randomised; 4. Number of children who withdraw/drop out, at the end of study, with feasibility measures collected throughout the study

2. Assessment measures of feasibility measured using study data on: 1. Number of children who complete all 3 assessment time points; 2. Time taken to complete assessments; 3. Number of children who complete all 6 screening assessment appointments; 4. Any issues with the outcome measures or screening tools will be recorded, at the end of the study, with feasibility measures collected throughout the study

Key secondary outcome(s)
1. Physical function measured using the Bruininks-Oseretsky Test of Motor Proficiency, Second Edition (BOT-II), Timed Up and Go (TUG), 10-metre walk test (10MWT) at baseline, 6 and 12 months

2. Participation measured using the Oxford foot and ankle questionnaire: this is a patient/parent-reported outcome measure, Lanksy Play performance scale at baseline, 6 and 12 months

3. Upper Limb coordination measured using 9-hole peg test at baseline, 6 and 12 months

4. Chemotherapy-related outcomes measured using the number of dose modifications or omissions of chemotherapy, cumulative dose of chemotherapy at baseline, 6 and 12 months

5. CIPN outcomes measured using the percentage of children in each group; a) identified as having CIPN, b) receiving medication management for CIPN at baseline, 6 and 12 months

6. Physiotherapy outcomes measured using the number of children who require orthotics, time from diagnosis to physiotherapy intervention (if any required) at baseline, 6 and 12 months

Completion date
30/06/2027

Eligibility

Key inclusion criteria
Newly diagnosed children, 4-<18 years at high risk of CIPN (this will encompass the following diagnoses: children with Acute Lymphoblastic Leukaemia (ALL), Wilms Tumour, Rhabdomyosarcoma, Low grade brain tumour on LGG 2 Protocol).
These children are classed as high risk of CIPN as their treatment protocol includes weekly vincristine during their treatment schedule. High incidence of CIPN in these patient groups has been reported in the literature.

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 Years

Upper age limit
17 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Medically unstable or presence of co-morbidities affecting safety of screening/outcome measure assessments, or those with relapsed disease.
2. Under the age of 4 years due to inability to complete the chosen outcome measures

Date of first enrolment
03/08/2023

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Alder Hey Children's NHS Foundation Trust
Alder Hey Hospital
Eaton Road
West Derby
Liverpool
England
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Sponsor information

Organisation
Alder Hey Children's NHS Foundation Trust

ROR
https://ror.org/00p18zw56

Funder(s)

Funder type

Funder Name
Charitable Funding at Alder Hey Children’s NHS Foundation Trust

Funder Name
Isle of Man Anti-Cancer Association

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available