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Therapeutic drug monitoring in children with cancer

Submission date	Recruitment status	[_] Prospectively registered
09/05/2019	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/05/2019	Ongoing	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/11/2024	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-measuring-the-levels-of-chemotherapy-in-the-blood-nccpg-tdm-2018 (added 23/04/2020)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
NCCPG TDM 2018

Study information

Scientific Title
A clinical pharmacology study to investigate the utility of therapeutic drug monitoring in challenging childhood cancer patient populations

Study objectives
The use of therapeutic drug monitoring relates to the measurement of drug levels in biological samples to individualise patient treatment through changing drug doses. This is conducted with a view to improving how effective the drug is and/or reducing side effects.

Over several years we have identified childhood cancer patients who clearly benefit from this treatment approach with commonly used cancer drugs. These 'hard to treat' patients include pre-term infants and newborn children, patients with no or poorly functioning kidneys, obese children and patients receiving high dose chemotherapy. The current study will allow us to maximise the information that is generated from treating patients in this way, with information relating to individual patient exposure and clinical outcome collected from a significant number of patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/01/2019, North East - Newcastle and North Tyneside 2 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Dr, Newcastle upon Tyne NE2 4NQ; 0207 104 8019; nrescommittee.northeast-newcastleandnorthtyneside2@nhs.net), ref: 18/NE/0384

Study design
Multi-centre basic science study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cancer

Interventions
The trial will recruit an estimated 150 patients within defined 'hard to treat' categories. These include pre-term infants and newborns, patients with impaired kidney function or no kidneys, patients receiving high dose chemotherapy, obese patients, and those receiving chemotherapy where the drug is injected directly into the tumour.
Patients will be referred to the study following decisions made by their treating clinician to use Therapeutic Drug Monitoring as part of the patient's standard treatment.
Clinical and response data will be collected following each cycle of treatment and all relevant clinical information and data generated will be entered into a patient registry in an anonymised form available only to registered medical staff with individual password-protected user accounts. Clinicians will then be able to use this information when treating future patients within these 'hard to treat' groups.

Intervention Type
Other

Primary outcome measure
Definition of the pharmacokinetics of widely used anti-cancer drugs in defined 'hard to treat' patient populations; assessment of factors associated with pharmacokinetic variability in defined 'hard to treat' patient populations.
Measured by analysis of samples from patients.
Time point - end of study.

Secondary outcome measures
1. Establishment of a national registry to provide access to data relating to the dosing of a comprehensive library of chemotherapeutic in defined 'hard to treat' patient populations.
Measured by analysis of samples from patients - data published on trial website.
Time point - ongoing throughout study as data become available.

2. Development of national treatment guidelines supporting the use of Therapeutic Drug Monitoring treatment strategies for patients treated in the UK and more widely.
Measured by analysis of samples from patients.
Time point - end of study.

Overall study start date
01/06/2018

Completion date
01/06/2029

Eligibility

Key inclusion criteria
1. Age <18 years.
2. Confirmed diagnosis of cancer.
3. Patient receiving a ‘non-standard’ strategy of chemotherapy delivery (see below for examples of patient groups that fall into this category).*

4. Appropriate venous access.
5. Request from the treating clinician for therapeutic drug monitoring approach to treatment.
6. Willingness to participate and written informed parental/patient consent (signed and dated).

* Patients receiving non-standard chemotherapy dosing regimens will include the following groups: pre-term infants and neonates, anephric patients, patients receiving high dose myeloablative chemotherapy, patients undergoing chemoembolisation procedures, obese patients (BMI at or above the 95th percentile for children of the same age and sex).

Participant type(s)
Patient

Age group
Child

Upper age limit
18 Years

Sex
Both

Target number of participants
150

Total final enrolment
168

Key exclusion criteria
Failure to meet the inclusion criteria.

Date of first enrolment
01/05/2019

Date of final enrolment
30/11/2028

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre

Royal Aberdeen Children's Hospital
Westburn Road
Aberdeen
United Kingdom
AB25 2ZG

Study participating centre
Birmingham Children's Hospital
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Study participating centre
Bristol Royal Hospital for Children
Upper Maudlin Street
Bristol
United Kingdom
BS2 8BJ

Study participating centre
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 2QQ

Study participating centre
Children's Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Royal Hospital for Sick Children, Edinburgh
Sciennes Road
Edinburgh
United Kingdom
EH9 1LF

Study participating centre
Royal Hospital for Sick Children, Glasgow
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
Great Ormond Street Hospital
Great Ormond Street
London
United Kingdom
WC1N 3JH

Study participating centre
Leeds General Infirmary,
Great George St
Leeds
United Kingdom
LS1 3EX

Study participating centre
Alder Hey Children's Hospital
Eaton Road
Liverpool
United Kingdom
L12 2AP

Study participating centre
Royal Manchester Children's Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne

United Kingdom
NE1 4LP

Study participating centre
Queens Medical Centre
Derby Rd
Nottingham
United Kingdom
NG7 2UH

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Sheffield Children's Hospital
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
University College Hospital London
250 Euston Road
London
United Kingdom
NW1 2PG

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Newcastle Joint Research Office
Level 1
Regent Point
Regent Farm Road
Gosforth
Newcastle upon Tyne
England
United Kingdom
NE3 3HD
0191 282 5959
trust.r&d@nuth.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be reported and disseminated by the following methods;
Peer reviewed scientific journals
Internal reports
Conference presentation
Publication on website

A registry of information produced from the study will also be made available on the study website to guide clinicians in the treatment of 'hard to treat' patient groups.

Publication will be at the end of the study, with interim updates given throughout the study. The registry will be populated throughout the
study as information becomes available..

Intention to publish date
01/12/2029

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article		16/11/2024	19/11/2024	Yes	No