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13-cis-retinoic acid monitoring study

Submission date 18/06/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/06/2010	**Overall study status** Completed	
Last Edited 04/04/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-blood-levels-of-the-drug-13cisretinoic-acid-in-children-and-young-people-with-neuroblastoma

Study website
http://cclg.powertrial.com/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2008-003606-33

IRAS number

ClinicalTrials.gov number
NCT00939965

Secondary identifying numbers
7898

Study information

Scientific Title
Pilot study to investigate the feasibility of 13-cis-retinoic acid pharmacokinetic monitoring in high-risk neuroblastoma patients

Acronym
PK 2008 03

Study objectives
This study is designed to implement pharmacokinetically guided 13-cis-retinoic acid (Roaccutane) dose adjustment in high-risk neuroblastoma patients. Pharmacokinetic sampling will be carried out on course 1 of treatment and patients who exhibit low drug plasma levels (less than 2 µM), in conjunction with minimal toxicity, will receive an increased dose of 13-cis-retinoic acid on course 2 of treatment. Additional pharmacokinetic sampling will be carried out to monitor plasma concentrations following administration of this increased dose of 13-cis-retinoic acid, again in conjunction with toxicity monitoring. Individualised dosing in patients will then be maintained in order to prevent potentially sub-therapeutic plasma concentrations of 13-cis-retinoic acid being experienced over the remainder of the 13-cis-retinoic acid treatment period. The aim of the study is to achieve consistent plasma concentrations of 13-cis-retinoic acid in high-risk neuroblastoma patients over the 6 month period of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Trent Research Ethics Committee, 15/01/2009, ref: 08/H0405/55

Study design
Multicentre non-randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Paediatric Oncology; Disease: Miscellaneous

Interventions
13-cis-retinoic acid (Isotretinoin) is administered orally to all patients at a dose of 160 mg/m2 /day (or 5.33 mg/kg/day for children under 12 kg). A course of treatment lasts for 14 days and patients receive a total of 6 courses, with a 14 day period between each course. Patients who experience peak plasma concentrations of Isotretinoin below 2 µM receive a 25% dose increase on the next course of treatment; patients who experience peak plasma concentrations of Isotretinoin below 1 µM receive a 50% dose increase on the next course of treatment. These dose adjustments are only carried out in patients experiencing minimal or no toxicity.

Depending on the results obtained from course 1, an additional 10 and a further 5 blood samples may be taken on course 2 and 3 respectively. Therefore, a maximum of 20 blood samples may be collected from patients over three courses of treatment.

Blood samples:
Five blood samples will be collected from patients at specific time points over a period of 6 hours following the first dose of 13-cis-retinoic acid administeration on day 14 of course 1 of treatment. In addition, a single blood sample will be taken prior to treatment with 13-cis-retinoic acid for genetic analysis.

Follow up length: 36 months
Study entry: registration only

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
13-cis-retinoic acid (Roaccutane)

Primary outcome measure
To examine the feasibility of implementing dose individualisation with 13-cis-retinoic acid (Roaccutane) monitoring in patients undergoing treatment. All outcome measures will be measured upon completion of the study.

Secondary outcome measures
1. To ensure that patients are not exposed to potentially sub-optimal plasma concentrations of 13-cis-retinoic acid during long-term treatment
2. To minimize the large inter-patient variation in plasma concentrations of 13-cis-retinoic observed following standard treatment with 13-cis-retinoic acid
3. To obtain preliminary data to investigate the potential impact of 13-cis-retinoic therapeutic monitoring on efficacy and toxicity

All outcome measures will be measured upon completion of the study.

Overall study start date
17/07/2009

Completion date
31/03/2015

Eligibility

Key inclusion criteria
1. Age less than 18 years at time of registration, either sex
2. Diagnosis of high-risk neuroblastoma
3. Receiving 13-cis-retinoic acid (Roaccutane) as part of clinical treatment
4. Single or double lumen central venous catheter in place
5. Written informed consent
6. Protocol approval by national and local ethics committee, regulatory authority and Trust R&D Departments
7. A negative pregnancy test for women of childbearing potential, and sexually active patients and partners agreeing to undertake adequate contraceptive measures

Participant type(s)
Patient

Age group
Child

Upper age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 75; UK sample size: 75

Total final enrolment
103

Key exclusion criteria
Failure to comply with any of the inclusion criteria

Date of first enrolment
17/07/2009

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northern Institute of Cancer Research
Newcastle Upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Royal Victoria Infirmary
Newcastle upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/01/2013	22/01/2019	Yes	No
Plain English results			04/04/2022	No	Yes
HRA research summary			28/06/2023	No	No