

13-cis-retinoic acid monitoring study

Submission date 18/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/04/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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>

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00939965

Clinical Trials Information System (CTIS)

2008-003606-33

Protocol serial number

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

Primary study design

Interventional

Study design

Multicentre non-randomised interventional treatment trial

Study type(s)

Treatment

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 administration 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(s)

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.

Key secondary outcome(s)

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 acid 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.

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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

18 Years

Sex

All

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

United Kingdom

England

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)

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, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/01/2013	22/01/2019	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			04/04/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes