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IMAT-Neuroblastoma

Submission date 13/02/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/02/2017	**Overall study status** Completed	
Last Edited 17/02/2025	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-intensity-modulated-arc-therapy-for-people-with-neuroblastoma-imat

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
CPMS 33136

Study information

Scientific Title

A randomised Phase I/II study of Intensity Modulated Arc Therapy techniques in abdominal neuroblastoma

Acronym
IMAT

Study objectives
The aim of this study is to determine the radiotherapy dose, possibly higher than is currently standard and feasible, delivered by either IMAT or conventional radiotherapy techniques, for use in a subsequent international randomised phase III study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Hampstead Research Ethics Committee, 21/12/2016, ref: 16/LO/2186

Study design
Randomized; Interventional; Design type: Treatment, Radiotherapy

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Cancer, Primary sub-specialty: Children's Cancer and Leukaemia; UKCRC code/ Disease: Cancer/ Malignant neoplasms of ill-defined, secondary and unspecified sites

Interventions
Participants will be randomised via paper-based telephone randomisation until the online remote database is live (https://www.cancertrials.bham.ac.uk/IMATlive). They will be randomised in a 1:1 ratio according to a computerised minimisation algorithm, developed by the Trial Office, stratified according to MYCN amplification, Stage L2 or M and completeness of surgery.

Arm A: Participants receive a dose of 21 Gy in 14 fractions over 3 weeks
Arm B: Participants receive a dose of 36 Gy in 24 Fractions over 5 weeks

The centre will then have four weeks after a planning scan to define the treatment area and work out a treatment plan for both IMAT and conventional radiotherapy and a central review board will decide on the best treatment for the patient.

All participants are followed up for the 30 days following the end of treatment to monitor for acute toxicity. Clinical assessments are every 6 months until 2 years post-randomisation date. Two years post randomisation there will be a local control assessment. Assessment as per local practice between 2-5 years post-randomisation. At 5 years post-randomisation there is a long-term toxicity assessment.

Intervention Type
Other

Primary outcome(s)
The actual dose delivered to patients in Gy, covering total Gy given and in how many fractions is captured by form following end of treatment.

Key secondary outcome(s))
1. Acute toxicity is assessed using information acquired by telephone consultation or clinic visit at least weekly for the thirty days following the end of treatment
2. Local control is assessed as per standard practice (mIBG scans and cross-sectional imaging are typically performed) at 2 years after randomisation. In the absence of any other imaging modality being indicated for other purposes, an ultrasound examination or MRI scan is preferred to avoid additional radiation exposure.
3. Long-term side effects are recorded at 5 years after the patient was randomised according to the Late Toxicity RTOG scoring system. This information will be collected during routine clinic visits; no trial-specific visits are required.
4. Event-free survival (EFS) and overall survival (OS) are captured using case report forms at each follow up visit/phone call whether the patient is still alive and whether there is progression /recurrence. This is captured weekly post-treatment up until the end of thirty days post-treatment, then every 6 months until 2 years post-randomisation, then as per local practise from 2 years up until 5 years post-randomisation.

Completion date
28/12/2025

Eligibility

Key inclusion criteria
1. Any patient with high-risk neuroblastoma of the abdominal or pelvic regions who requires radical radiotherapy
2. Fit to receive radical radiotherapy
3. Aged 18 months or over at diagnosis
4. Informed consent from patient, parent or guardian
5. Documented negative pregnancy test for female patients of childbearing potential
6. Patient agrees to use effective contraception during the treatment period (patients of childbearing age)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 months

Sex
All

Total final enrolment
50

Key exclusion criteria
Pregnant patient

Date of first enrolment
21/02/2017

Date of final enrolment
14/08/2020

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
University College Hospital
235 Euston Road
Fitzrovia
London
United Kingdom
NW1 2BU

Study participating centre
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre

Belfast City Hospital
51 Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Clatterbridge Cancer Centre
Lower Lane
Fazakerley
Liverpool
United Kingdom
L9 7AL

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Gartnavel Hospital
1053 Great Western Road
Glasgow

United Kingdom
G12 0YN

Study participating centre
Christie NHS Foundation Trust
550 Wilmslow Road
Manchester
United Kingdom
M20 4BX

Study participating centre
The Queen Elizabeth Hospital
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH

Study participating centre
The Royal Marsden Hospital
203 Fulham Road
Chelsea
London
United Kingdom
SW3 6JJ

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

Study participating centre
St. James University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Velindre Cancer Centre
Velindre Road
Cardiff
United Kingdom
CF14 2TL

Study participating centre
Weston Park Hospital
Whitham Road
Sheffield
United Kingdom
S10 2SJ

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Cancer Research 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

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			20/06/2024	No	Yes
Protocol file	version v3.0	15/05/2018	22/07/2020	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes