

HR-NBL2 Newsletter



Randomized, international and multicentric phase 3 study that evaluates and compares 2 treatment strategies in 3 therapeutic phases (INDUCTION, HIGH DOSE CHEMOTHERAPY AND RADIOTHERAPY) for patients with high-risk neuroblastoma



August 2023

Issue 2

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Message from UK National Coordinator Dr Martin Elliott:

“Great to see many sites now open and others due to open imminently and recruitment is at expected monthly accrual. Please contact me about any issues that you encounter with trial treatment, protocol investigations etc. We will be in touch soon about protocol 3.0 amendment, which will allow patients with inadequate response to induction chemotherapy to continue on trial to tandem high-dose chemotherapy.”

BW



International Sponsor

Gustave Roussy

International Coordinating Investigator

Dr Dominique Valteau-Couant

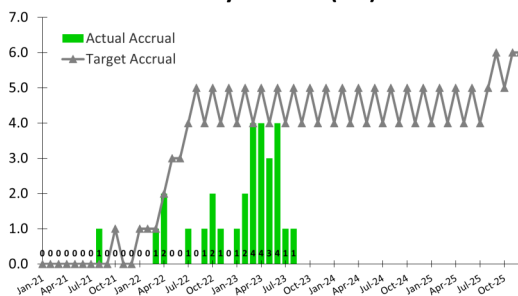
HR-NBL2 News

RECRUITMENT MEETS MONTHLY TARGET

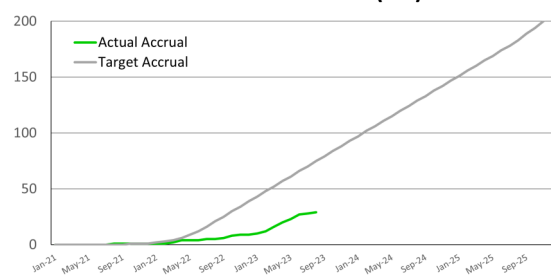
Thank you to the sites who have opened to recruitment since the trial opened In Aug 2021.

We are pleased to report that the trial has achieved the target monthly UK recruitment of 3-4 patients per month for the period Mar-Jul 2023! But we still have a way to go to meet the overall target of 206 by Dec 2025. We can only achieve this with your help! We need all remaining hospitals open to recruitment to be able to offer this trial to as many patients as possible.

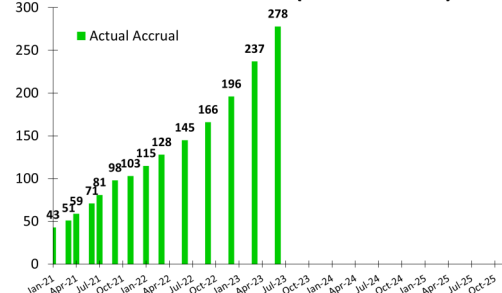
Monthly Accrual (UK)



Cumulative Accrual (UK)



Cumulative Accrual (International)



International update

291 patients had enrolled on the trial internationally to 02-Aug-2023. This is 36% of the trial's 800-patient recruitment target by 31-Dec-2025.



CANCER RESEARCH UK

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UNIVERSITY OF BIRMINGHAM

UK Site opening

Thank you to the sites who have opened to recruitment since the trial opened. In Aug 2021. We need your help to open the remaining hospitals! Please keep in touch with any queries or problems seen during set up and we will do everything we can to help.

Site	Date Opened	Patients Recruited
Bristol Royal Hospital for Children	26-Aug-2021	3
Royal Marsden Hospital	03-Mar-2021	7
The Christie Hospital	01-Apr-2022	N/A
Royal Hospital for Children Glasgow	08-Apr-2022	3
Royal Manchester Children's Hospital	07-Sep-2022	3
Addenbrooke's Hospital, Cambridge	22-Sep-2022	3
Birmingham Children's Hospital	09-Dec-2022	3
Queen Elizabeth Hospital, B'ham	09-Dec-2022	N/A
Royal Victoria Infirmary, Newcastle	15-Dec-2022	4
Sheffield Children's Hospital	20-Dec-2022	1
Alder Hey Hospital, Liverpool	08-Mar-2023	1
Leeds General Infirmary	17-Apr-2023	1
John Radcliffe, Oxford	02-Aug-2023	0

Sites not yet open	
Royal Aberdeen Children's Hospital	Southampton General Hospital
Royal Belfast Hospital for Sick Children	Nottingham Children's Hospital
Royal Hospital for Sick Children, Edinburgh	University College London Hospital
Great Ormond Street Hospital, London	Weston Park Hospital, Sheffield
Leicester Royal Infirmary	Velindre Hospital, Cardiff
Children's Hospital for Wales, Cardiff	

GOSH and UCLH are opening very soon!

Watch out for a **CRF Completion Guidelines** document coming soon! We hope to cover most of the common queries raised when completing the database. If you have any to add, let us know!

Reminders

- Please remember to complete eCRFs with any **status updates** for your patients as soon as possible after the event (e.g. progression, death)
- Remember to **send images for RTQA review** to QUARTET for all patients (randomised and non-randomised) prior to starting radiotherapy
- Ensure all scan images, notes and correspondence sent to QUARTET and the Trial Office **do not contain any patient identifiers** (TNO only)
- Remember to use **"XX"** instead of initials when enrolling patients on the database

Always contact the CRCTU Trial Office with all queries. If we can't help, we will raise any issues with the Sponsor and report back.



UK National Coordinator

Dr Martin Elliott

UK National

Coordinating Centre

Cancer Research UK Clinical Trials Unit,
University of Birmingham

CONTACT US

Trial Coordinators

Salma Iqbal, Hannah Jeffery

Senior Trial Coordinator

Jennifer Laidler

Trial Administrator

Faiza Suleman

E-mail:

HighRisk-NBL2@trials.bham.ac.uk

Tel: 0121 414 3799

Fax: 0121 414 9520

By Post:

HR-NBL2 Trials Office

Children's Cancer Trials Team

Cancer Research UK Clinical Trials Unit,

Institute of Cancer and Genomic Sciences,

University of Birmingham,

Edgbaston, Birmingham,
B15 2TT

CLINICAL QUERIES

Clinical queries during office hours should be directed to the

UK Trials Office

SAE REPORTING

Report SAEs to Gustave Roussy online via My eClinical web portal

<https://www.everreport.eu/myeclinical/form/IGR/login.php>

If portal access is unavailable FAX forms to: +33 (0) 1 42 11 61 50