HR-NBL2 Newsletter

SIOPEN R-NET

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

Solving Kids' Cancer UK

NEUROBLASTOMA UK
FIGHTING CHILDHOOD CANCER

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Issue 4

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GUSTAVE ROUSSY
CANCER CAMPUS
GRAND PARIS

International Sponsor

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Message from CRCTU Trials Team

We would like to thank all the staff across all our hospitals for their incredible hard work on HR-NBL2. 2024 has started off as a wonderful year with a new site open and reaching the 50-patient milestone. We hope to sustain this momentum for the remainder of the year and open the remaining sites as soon as possible. We hope you find this newsletter helpful with the updates on the trial, guidance for TEMIRI patients and the recent sub-stantial amendment

HR-NBL2 News

Thank you to the sites for their incredible hard work in ensuring the trial is running smoothly.

Recruitment dropped to 2-3 patients per month across Jan-March 2024. This is disappointing as we had been averaging 4 patients per month at the end of last year but we remain hopeful that numbers will pick up! We are asking all centres in set-up to complete this urgently and all centres open for the trial to keep looking out for potential patients. Please let us know any reasons for patients declining the trial.

Site update (UK)

We are pleased to announce that Aberdeen opened to recruitment on 22nd of March!

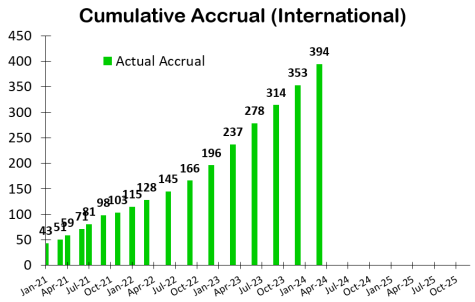
We are continuously working hard to open the remaining sites.

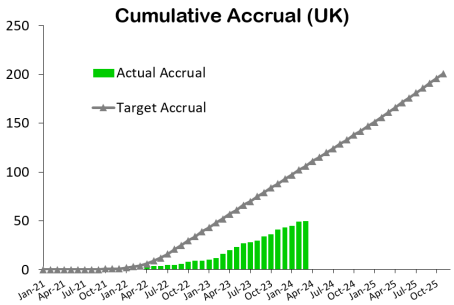
Recruitment update (UK)

As of March 2024 we have recruited 50 patients in total which is 24.27% of the UK's overall target. We are continuing to work to achieve our target of 206 by December 2025.

International update

394 patients had enrolled on the trial internationally to 25-Mar-2024. This is 49% of the trial's 800-patients recruitment target by 31-Dec-2025. We are almost half-way there!!





Country	Number of Patients Recruited
France	206
UK	45
The Netherlands	33
Italy	29
Greece	14
Switzerland	11
Denmark	8
Belgium	5
Czech Republic	5
Norway	5
Australia	3
Germany	3
Austria	2
Slovenia	1
Total recruited up to 01-Feb-2024	**370**

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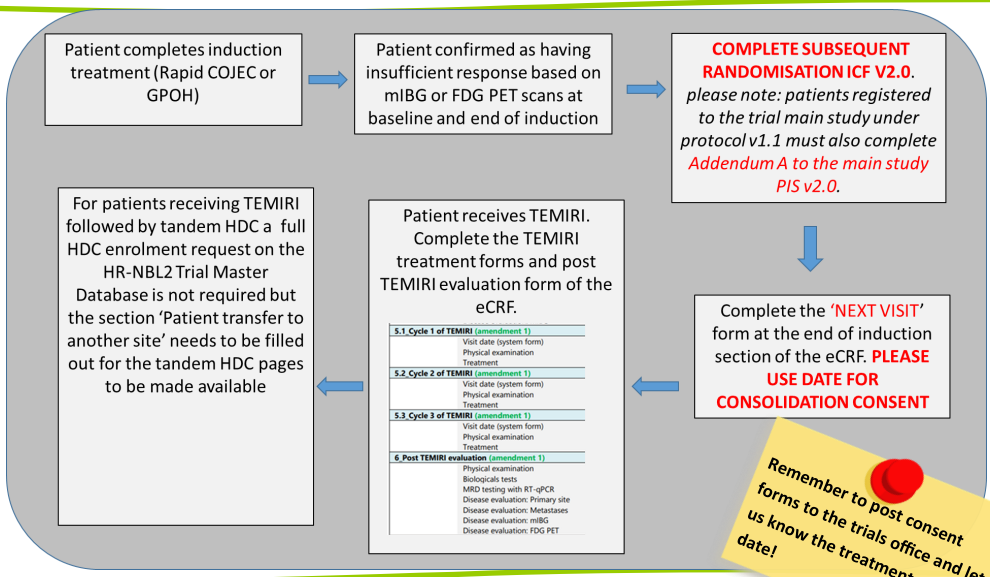
UK sites not yet open
Southampton General Hospital
Nottingham Children's Hospital
Velindre Hospital, Cardiff
Royal Hospital for Sick Children, Edinburgh
Weston Park Hospital, Sheffield
Leicester Royal Infirmary
Children's Hospital for Wales, Cardiff

Guidance for TEMIRI



Amendments

SA08 was distributed to sites on 17-Jan-2024. This amendment incorporates Protocol v3.0, PIS v2.0, ICF v2.0, and changes to the SoECAT and IRAS forms. This was initially submitted to UK regulatory authorities as SA07, and was fully approved as SA08 (with the addition of a UK Protocol Appendix)

- **Substantial Amendment 8 (SA08) was approved in January with no changes to the IRAS form from SA07.**
- **The 35-day objection period for SA08 ended on February 21, 2024. Sites are encouraged to confirm capacity and capability promptly.**

Reminders

- **Please remember to complete eCRFs with any status updates for your patients as soon as possible after the event (e.g. progression, death)**
- **Patients in follow up, please remember to complete the follow up forms timely. You will need to add forms for each visit in each year.**
- **For patients enrolling onto TEMIRI, remember to complete the subsequent randomisation consent form for consolidation before they start TEMIRI and email us the start dates of the treatment for TEMIRI and tandem HDC.**
- **Remember to redact patient identifiers when sending emails to the trials office, and use "XX" instead of initials when enrolling patients.**
- **Please return the receipt for TEMIRI consent guidelines.**
- **Remember to post all consent forms to the trials office as soon as possible.**

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,

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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.evereport.eu/myeclinical/form/IGR/login.php

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