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A study to see if earlier and more hormonal testing can detect problems sooner in patients who have had radiotherapy treatment for brain tumours

Submission date 18/06/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 02/07/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 19/06/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

After radiotherapy for brain tumours, some patients can develop hormone problems because of the effects on the brain's hormone control centre. Right now, hormone levels are usually only checked once, a year after treatment ends. The ENDORADS study wants to find out if checking hormone levels more often—every four months for two years—can help spot problems earlier. This could mean patients get treatment sooner, which might reduce long-term side effects. The study will also look at whether this more frequent testing works well for both patients and hospitals.

Who can participate?

The study is for people who have had radiotherapy to the brain for a primary brain tumour and meet certain medical criteria. A doctor will check if someone is eligible to take part.

What does the study involve?

If you join the study, your hormone levels will be tested every four months for two years after your radiotherapy ends. These tests are usually done through blood samples. The study team will monitor your results and share them with your medical team, who will decide if any treatment is needed.

What are the possible benefits and risks of participating?

The main benefit is that hormone problems might be found and treated earlier, which could help reduce long-term health issues. The risks are small and mainly related to the inconvenience of more frequent blood tests, which some people may find uncomfortable or time-consuming.

Where is the study run from?

University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
October 2024 to September 2028.

Who is funding the study?
Stand Up To Cancer and Cancer Research UK.

Who is the main contact?
endorads@trials.bham.ac.uk

Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
358898

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RG_24-069

Study information

Scientific Title
Early eNDOcrine intervention after brain RADiotherapy feasibility Study

Acronym
ENDORADS

Study objectives
Earlier and more frequent hormonal and metabolic testing will detect hormonal and metabolic deficiencies sooner after radiotherapy treatment

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted, unknown (unknown, Unknown, unknown, United Kingdom; unknown; Email not provided), ref: Reference number not provided

Study design
Multicenter interventional feasibility study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Tumour of the central nervous system where 10Gy or more radiotherapy has been received to the hypothalamus or pituitary gland

Interventions
Patients who have had radiotherapy for a brain tumour will be approached to take part in the study. When they have consented, they will undergo hormonal and metabolic testing every 4 months from the end of their radiotherapy treatment until 2 years after the end of radiotherapy. They will have 6 testing timepoints in this period. There is no follow-up period, therefore participants will be on study for 2 years.

Intervention Type
Procedure/Surgery

Primary outcome(s)

Time to develop biochemical Growth Hormone deficiency
Time from end of radiotherapy treatment to develop biochemical Growth Hormone deficiency is defined as the difference between date of end of radiotherapy treatment and date of the first abnormal Growth Hormone test, as defined by each site's local range. Biochemical Growth Hormone deficiency will be defined if the test results of the dynamic testing for Growth Hormone are abnormal.

Key secondary outcome(s))

1. Time to develop Growth Hormone deficiency is measured using local diagnosis based on dynamic testing for Growth Hormone, IGF-1, IGFBP3, height velocity, and weight velocity at baseline and follow-up timepoints
2. Time to develop Growth Hormone deficiency is measured using central diagnosis based on central review of dynamic testing for Growth Hormone, IGF-1, IGFBP3, height velocity, and weight velocity at baseline and follow-up timepoints
3. Proportion of patients with completed testing is measured using test completion records at each timepoint
4. Number of hypothalamic-pituitary axes with documented deficiency is measured using local reference ranges for ACTH/Cortisol, thyroid, gonadotropin, prolactin, and arginine vasopressin axes at each timepoint
5. Time to develop measurable hypothalamic-pituitary deficiency is measured using local reference ranges for each axis based on the date of first abnormal test result at baseline and follow-up timepoints
6. Number of hypothalamic-pituitary axes with documented deficiency is measured using local diagnosis based on site review of hypothalamic-pituitary tests at each timepoint
7. Time to develop measurable hypothalamic-pituitary deficiency is measured using local diagnosis based on site review of hypothalamic-pituitary tests at baseline and follow-up timepoints
8. Number of hypothalamic-pituitary axes with documented deficiency is measured using central diagnosis based on central review of hypothalamic-pituitary tests at each timepoint
9. Time to develop measurable hypothalamic-pituitary deficiency is measured using central diagnosis based on central review of hypothalamic-pituitary tests at baseline and follow-up timepoints
10. Number of metabolic tests with documented dysfunction is measured using local reference ranges for glucose, insulin, HbA1c, lipids, liver function, blood pressure, and BMI at each timepoint
11. Time to develop metabolic dysfunction is measured using local reference ranges for each metabolic test and overall dysfunction based on the date of first abnormal test result at baseline and follow-up timepoints
12. Number of metabolic tests with documented dysfunction is measured using local diagnosis based on site review of metabolic tests at each timepoint
13. Time to develop metabolic dysfunction is measured using local diagnosis based on site review of metabolic tests at baseline and follow-up timepoints
14. Number of metabolic tests with documented dysfunction is measured using central diagnosis based on central review of metabolic tests at each timepoint
15. Time to develop metabolic dysfunction is measured using central diagnosis based on central review of metabolic tests at baseline and follow-up timepoints
16. Proportion of patients who receive treatment is measured using treatment records for each axis within one and two years of end of radiotherapy
17. Time to treatment is measured using treatment records for each axis based on the date of treatment initiation within one and two years of end of radiotherapy

18. Reasons for non-treatment where deficiencies are identified are measured using clinical documentation for each test

Completion date
28/09/2028

Eligibility

Key inclusion criteria
1. Aged 25 years or under at the end of cranial radiotherapy
2. Cranial irradiation for a primary central nervous system tumour
3. Trial recruitment within 8 months of the completion of cranial irradiation. If craniospinal radiotherapy is given, the cranial component must have completed within the previous 8 months
4. Hypothalamic or pituitary dose of ≥ 10 Gy
5. Written informed consent from the patient and/or parent/legal guardian

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
0 years

Upper age limit
25 years

Sex
All

Key exclusion criteria
1. Serial dynamic hypothalamic assessments not possible due to social, geographic or psychological reasons
2. Patients with a hypothalamic-pituitary (HP) axis tumour having hypopituitarism including Growth Hormone deficiency at tumour diagnosis or after surgery
3. Patients with evidence of Growth Hormone deficiency
4. Females who are pregnant or breastfeeding

Date of first enrolment
29/09/2025

Date of final enrolment
28/09/2026

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Birmingham Children's Hospital
Steelhouse Lane
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B4 6NH

Study participating centre
Great Ormond Street Hospital
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Sheffield Children's NHS Foundation Trust
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Study participating centre
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type

Charity

Funder Name
Stand Up To Cancer

Alternative Name(s)
Unidos Contra El Cáncer, SU2C

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

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 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