

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

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<b>Registration date</b> 02/07/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/06/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

**Type(s)**  
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  $\geq 10$  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

Birmingham

United Kingdom

B4 6NH

**Study participating centre**

**Great Ormond Street Hospital**

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**Study participating centre**

**Alderhey**

Eaton Road

West Derby

Liverpool

United Kingdom

L12 2AP

**Study participating centre**

**Sheffield Children's NHS Foundation Trust**

Western Bank

Sheffield  
United Kingdom  
S10 2TH

**Study participating centre**  
**Greater Glasgow and Clyde**  
Gartnavel Royal Hospital  
1055 Great Western Road  
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United Kingdom  
G12 0XH

**Study participating centre**  
**University Hospitals Bristol and Weston NHS Foundation Trust**  
Trust Headquarters  
Marlborough Street  
Bristol  
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BS1 3NU

**Study participating centre**  
**The Christie**  
550 Wilmslow Road  
Withington  
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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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes