

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 | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 02/07/2025 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 19/06/2025 | Condition category 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

Contact name

Dr Martin McCabe

ORCID ID

<https://orcid.org/0000-0002-5138-0707>

Contact details

The Christie NHS Foundation Trust, Wilmslow Road, Withington
Manchester
United Kingdom
M20 4BX
+44 1614463000
martin.mccabe@nhs.net

Type(s)

Public

Contact name

Dr Helen Stone

ORCID ID

<https://orcid.org/0000-0001-9886-0161>

Contact details

CRCTU, University of Birmingham, Vincent Drive, Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 121 414 8040
endorads@trials.bham.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

358898

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

Birmingham

United Kingdom

B4 6NH

Study participating centre

Great Ormond Street Hospital

Great Ormond Street

London

United Kingdom

WC1N 3JH

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
Glasgow
United Kingdom
G12 0XH

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

Study participating centre
The Christie
550 Wilmslow Road
Withington
Manchester
United Kingdom
M20 4BX

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