

Radiation versus observation following surgical resection of atypical meningioma

Submission date 19/05/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/05/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/07/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-radiotherapy-after-surgery-for-a-type-of-brain-tumour-called-meningioma-roam-eortc-1308>

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

HTA 12/173/14

Study information

Scientific Title

Radiation versus Observation following surgical resection of Atypical Meningioma: a randomised controlled trial (the ROAM trial)

Acronym

ROAM

Study objectives

Current hypothesis as of 03/05/2017:

To determine whether early adjuvant fractionated radiotherapy reduces the risk of tumour recurrence or death due to any cause compared to active monitoring in newly diagnosed atypical meningioma.

Previous hypothesis:

To determine whether early adjuvant fractionated external beam radiotherapy reduces the risk of tumour recurrence compared to active monitoring in newly diagnosed atypical meningioma.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee North East - Newcastle & North Tyneside 2, 12/02/2015, ref: 15/NE/0013

Study design

Two-arm multi-centre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Atypical meningioma

Interventions

The trial will randomise patients who have undergone gross total surgical resection of atypical (grade II) meningioma in a 1:1 ratio to either early radiotherapy (intervention) or active monitoring (comparator). Web-based randomisation will be used in this trial. Patients will be followed up for 60 months post randomisation by collecting information on signs/symptoms of tumour recurrence, 6 monthly MRI, recording of adverse events, quality of life questionnaires and cognitive function tests.

Intervention Type

Device

Phase

Phase III

Primary outcome(s)

Current primary outcome measure as of 05/04/2019:

Time to MRI evidence of tumour recurrence or death due to any cause (disease free survival [DFS]). (DFS will be counted from the date of surgery until the date of MRI evidence of tumour recurrence or death due to any cause. Only clear dural thickening as identified by the investigator is to be considered tumour.)

Previous primary outcome measure:

Time to MRI evidence of tumour recurrence [disease free survival (DFS)] is assessed at baseline, 6 and 12 months following surgery and annually thereafter for a minimum of 5 years post-surgery.

Key secondary outcome(s)

Current secondary outcome measures as of 05/04/2019:

1. Toxicity of radiotherapy assessed by CTCAE (Common Terminology Criteria for Adverse Events)
2. Quality of life
3. Neurocognitive function (UK sites only)
4. Time to second line (salvage) treatment (surgery, radiotherapy, radiosurgery)
5. Time to death (overall survival [OS])
6. Health economic analysis (incremental cost per QALY gained) (UK sites only)

Previous secondary outcome measures:

1. Time to second line (salvage) treatment (surgery, radiotherapy, radiosurgery)
2. Time to death [overall survival (OS)]
3. Toxicity assessed by Common Terminology Criteria for Adverse Events (CTCAE)
4. Quality of life is measured using the EORTC C30 and BN20 questionnaires
5. Neurocognitive function is measured using patient testing at baseline and 24 months
6. Health economic analysis (incremental cost per QALY gained) (UK sites only)

Patients will be assessed at baseline, 6 and 12 months following surgery and annually thereafter for a minimum of 5 years post-surgery unless otherwise stated.

Completion date

31/03/2026

Eligibility

Key inclusion criteria

Current inclusion criteria as of 03/05/2017:

1. Histologically confirmed newly diagnosed solitary atypical meningioma (WHO grade II) based on the 2016 WHO criteria
2. Age \geq 16 years
3. All anatomical locations allowed except optic nerve sheath tumour
4. Complete resection (Simpson 1, 2 or 3) as assessed by the surgeon
5. Able to commence radiotherapy between within 12 weeks of surgery (ideally 8-12 weeks)
6. WHO performance status 0, 1 or 2
7. Women of reproductive potential must use effective contraception for the whole duration of the treatment
8. Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial

Previous inclusion criteria:

1. Histologically confirmed newly diagnosed solitary atypical meningioma (WHO grade II) based on the 2007 WHO criteria
2. Age 16 years or over
3. All anatomical locations allowed except optic nerve sheath tumour
4. Complete resection (Simpson grade I, II or III) as assessed by the surgeon
5. Able to commence radiotherapy between 8 and 12 weeks after surgery
6. WHO performance status 0-2

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

157

Key exclusion criteria

Current exclusion criteria as of 05/04/2019:

1. Neurofibromatosis type II (NF-2)
2. Optic nerve sheath tumours
3. Multiple meningiomas
4. Radiation-induced meningioma
5. Clinical evidence of second malignancy, except for cervix carcinoma in situ or basal cell carcinoma, and history of invasive malignancy unless treated with curative intent and the patient

has been disease free for the last five years

6. Previous intracranial tumour in the last 10 years treated with radiotherapy or chemotherapy

7. Pregnant or lactating women.

Previous exclusion criteria as of 03/05/2017:

1. Neurofibromatosis type II (NF-2)

2. Optic nerve sheath tumours

3. Multiple meningiomas

4. Radiation-induced meningioma

5. Clinical evidence of second malignancy, except for cervix carcinoma in situ or basal cell carcinoma, and history of invasive malignancy unless treated with curative intent and the patient has not been disease free for the last five years

6. Previous intracranial tumour

7. Pregnant or lactating women

Previous exclusion criteria:

1. Neurofibromatosis type II (NF-2)

2. Multiple meningiomas

3. Previous radiotherapy to the brain or meninges interfering with the protocol treatment plan

4. Clinical evidence of second malignancies, except a history of cervix carcinoma in situ and/or basal cell carcinoma

5. Pregnant or lactating women

Date of first enrolment

28/04/2016

Date of final enrolment

26/05/2021

Locations

Countries of recruitment

United Kingdom

England

Northern Ireland

Scotland

Wales

Australia

Austria

Belgium

France

Germany

Ireland

Italy

New Zealand

Spain

Switzerland

Study participating centre

The Walton Centre

Liverpool

United Kingdom

L9 7LJ

Study participating centre

Queen's Hospital

Romford

United Kingdom

RM7 0AG

Study participating centre

CHU UCL Namur – Site Sainte-Elisabeth

Namur

Belgium

5000

Study participating centre

Nottingham City Hospital

Nottingham

United Kingdom

NG5 1PB

Study participating centre

Addenbrooke's Hospital

Cambridge

United Kingdom

CB2 0QQ

Study participating centre

Churchill Hospital

Oxford
United Kingdom
OX3 7LE

Study participating centre

Salford Royal Hospital

Manchester
United Kingdom
M6 8HD

Study participating centre

Hopitaux Universitaires Bordet-Erasme - Institut Jules Bordet

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Belgium
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Study participating centre

University College London Hospital

London
United Kingdom
NW1 2BU

Study participating centre

Western General Hospital

Edinburgh
United Kingdom
EH4 2XU

Study participating centre

Bristol Haematology and Oncology Centre

Bristol
United Kingdom
BS2 8ED

Study participating centre

Universitair Ziekenhuis Antwerpen

Antwerp
Belgium
2650

Study participating centre

Medical University Vienna - General Hospital AKH

Vienna
Austria
1090

Study participating centre

Charing Cross Hospital (Imperial College)

London
United Kingdom
W6 8RF

Study participating centre

Onze Lieve Vrouw Ziekenhuis

Aalst
Belgium
-

Study participating centre

University Hospital Southampton NHS Foundation Trust

Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre

King's College Hospital NHS Foundation Trust

Denmark Hill
Brixton
London
United Kingdom
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Study participating centre
Complejo Hospitalario de Navarra
Pamplona
Spain

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Study participating centre
Plymouth Hospitals NHS Trust
Derriford Road
Crownhill
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United Kingdom
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Study participating centre
Institut Catala d'Oncologia - ICO Badalona - Hospital Germans Trias i Pujol
Barcelona
Spain

-

Study participating centre
Royal Brisbane and Women's Hospital
Brisbane
Australia

-

Study participating centre
Institut Catala d'Oncologia - ICO Girona - Hospital Doctor Josep Trueta
Girona
Spain

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Study participating centre
Liverpool Hospital
Sydney
Australia

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Study participating centre

Newcastle upon Tyne Hospitals NHS Foundation Trust

Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre

Assistance Publique - Hopitaux de Paris - La Pitie Salpetriere

Paris
France

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Study participating centre

UniversitaetsSpital Zurich

Zurich
Switzerland

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Study participating centre

Sheffield Teaching Hospitals NHS Foundation Trust

Royal Hallamshire Hospital
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Study participating centre

CHRU Lille

Lille
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Study participating centre

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1055 Great Western Rd
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Universitaetsspital Basel
Basel
Switzerland

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Study participating centre
Royal North Shore Hospital
Sydney
Australia

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Study participating centre
SLRON Beaumont
Dublin
Ireland

-

Study participating centre
Peter MacCallum Cancer Centre
Melbourne
Australia

-

Study participating centre
CHU Lyon - Hopital neurologique Pierre Wertheimer
Lyon
France

-

Study participating centre
Waikato Hospital
Hamilton
New Zealand

-

Study participating centre

Christchurch Hospital

Christchurch
New Zealand

-

Study participating centre

Ospedale Bellaria

Bologna
Italy

-

Study participating centre

Paracelsus Kliniken

Germany

-

Study participating centre

University Hospitals Birmingham NHS Foundation Trust

Queen Elizabeth Hospital Birmingham
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre

Belfast Health and Social Care Trust

Belfast City Hospital
Lisburn Road
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BT9 7AB

Study participating centre

Hôpitaux universitaires de Genève - HUG - site de Cluse-Roseraie

Geneva
Switzerland

-

Study participating centre

Calvary Mater Newcastle

Newcastle

Australia

-

Study participating centre

Princess Alexandra Hospital

Sydney

Australia

-

Study participating centre

ROPART (Radiation Oncology Princess Alexandra Hospital Raymond Terrace)

Brisbane

Australia

-

Study participating centre

GasthuisZusters Antwerpen - Sint-Augustinus

Antwerp

Belgium

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Study participating centre

University Hospitals of North Midlands NHS Trust

Royal Stoke University Hospital

Newcastle Road

Stoke-on-Trent

United Kingdom

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Study participating centre

Cliniques Universitaires Saint-Luc

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Velindre NHS Trust

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Westmead Hospital

Sydney
Australia

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Centre Hospitalier Universitaire Vaudois - Lausanne

Lausanne
Switzerland

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Study participating centre

Fondazione IRCCS Istituto Neurologico Carlo Besta

Milan
Italy

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Study participating centre

Institut Catala d'Oncologia - Hospital Duran i Reynals

Barcelona
Spain

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Study participating centre

Chris O'Brien Lifehouse

Sydney
Australia

-

Study participating centre

Sir Charles Gairdner Hospital

Nedlands

Australia

-

Study participating centre

Universitaetsklinikum Bonn

Bonn

Germany

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Study participating centre

Hospital Universitario 12 De Octubre

Madrid

Spain

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Study participating centre

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London

United Kingdom

SW3 6JJ

Study participating centre

Innsbruck Universitaetsklinik

Innsbruck

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Sponsor information

Organisation

The Walton Centre NHS Foundation Trust (UK)

ROR

<https://ror.org/05cvxat96>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

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?
Protocol article	protocol	14/11/2015		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	qualitative analysis	01/04/2020	12/02/2020	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes