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Radiation versus observation following surgical resection of atypical meningioma

Submission date 19/05/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/05/2014	**Overall study status** Ongoing	
Last Edited 26/07/2022	**Condition category** Cancer	

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

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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 >/= 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

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The Walton Centre
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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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Study participating centre
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United Kingdom
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Study participating centre
Royal Brisbane and Women’s Hospital
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Australia
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Study participating centre
Institut Catala d'Oncologia - ICO Girona - Hospital Doctor Josep Trueta
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Study participating centre
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Australia
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Study participating centre

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Study participating centre
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Royal North Shore Hospital
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Australia
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Study participating centre
SLRON Beaumont
Dublin
Ireland
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Study participating centre
Peter MacCallum Cancer Centre
Melbourne
Australia
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Study participating centre
CHU Lyon - Hopital neurologique Pierre Wertheimer
Lyon
France
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Study participating centre
Waikato Hospital
Hamilton
New Zealand
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Study participating centre

Christchurch Hospital
Christchurch
New Zealand
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Study participating centre
Ospedale Bellaria
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Paracelsus Kliniken
Germany
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Calvary Mater Newcastle
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Study participating centre
Princess Alexandra Hospital
Sydney
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Study participating centre
ROPART (Radiation Oncology Princess Alexandra Hospital Raymond Terrace)
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Study participating centre
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Spain
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Study participating centre
Chris O'Brien Lifehouse
Sydney
Australia
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Study participating centre

Sir Charles Gairdner Hospital
Nedlands
Australia
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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	qualiatative analysis	01/04/2020	12/02/2020	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes