ISRCTN71502099 https://doi.org/10.1186/ISRCTN71502099

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

Study website
http://www.roam-trial.org.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/09/2014

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

Age group
Adult

Sex
Both

Target number of participants
190

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
Australia

Austria

Belgium

England

France

Germany

Ireland

Italy

New Zealand

Northern Ireland

Scotland

Spain

Switzerland

United Kingdom

Wales

Study participating centre
The Walton Centre
Liverpool
United Kingdom
L9 7LJ

Study participating centre
Queen's Hospital
Romford
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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
Brussels
Belgium
1000

Study participating centre
University College London Hospital
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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
Universitaur 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
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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
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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
-

Study participating centre
Liverpool Hospital
Sydney
Australia
-

Study participating centre
Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
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Newcastle upon Tyne
United Kingdom
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Study participating centre
Assistance Publique - Hopitaux de Paris - La Pitie Salpetriere
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France
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Study participating centre
UniversitaetsSpital Zurich
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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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1055 Great Western Rd
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Study participating centre
Universitaetsspital Basel
Basel
Switzerland
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Study participating centre
Royal North Shore Hospital
Sydney
Australia
-

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
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Study participating centre
Belfast Health and Social Care Trust
Belfast City Hospital
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United Kingdom
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
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Study participating centre
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Westmead Hospital
Sydney
Australia
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Study participating centre
Centre Hospitalier Universitaire Vaudois - Lausanne
Lausanne
Switzerland
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Study participating centre

Fondazione IRCCS Istituto Neurologico Carlo Besta
Milan
Italy
-

Study participating centre
Institut Catala d'Oncologia - Hospital Duran i Reynals
Barcelona
Spain
-

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
Royal Marsden NHS Foundation Trust
Fulham Road
London

United Kingdom
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Study participating centre
Innsbruck Universitaetsklinik
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Austria
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Sponsor information

Organisation
The Walton Centre NHS Foundation Trust (UK)

Sponsor details
Lower Lane
Fazakerley
Liverpool
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United Kingdom
L9 7LJ

Sponsor type
Hospital/treatment centre

Website
https://www.thewaltoncentre.nhs.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, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The communication and dissemination strategy will actively involve participating centres, their staff, service users and the professional bodies involved (Society of British Neurological Surgeons, British Neuro-Oncology Society) and relevant charitable organisations (brainstrust, The Brain Tumour Charity, MeningiomaUK), in discussing the proposed trial prior to its implementation and reviewing trial progress and results. Communication and dissemination of results, including findings from the embedded qualitative study relevant to clinical trial methodology, will be assisted by members of the study team, several of whom have leading roles in research and quality of practice activities across the NHS. Findings of the trial will be presented at National and International meetings of relevant professional bodies and research groups. The results of the trial will be published in peer-reviewed journals. Publication is anticipated in 2024/2025. Updates on trial progress will be presented at conferences throughout the recruitment period.

Intention to publish date
30/09/2026

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
Other publications	qualiatative analysis	01/04/2020	12/02/2020	Yes	No
HRA research summary			28/06/2023	No	No