ISRCTN57947111 https://doi.org/10.1186/ISRCTN57947111

Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma

Submission date	Recruitment status	[_] Prospectively registered
21/10/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/10/2022	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-radiotherapy-after-surgery-treat-type-brain-tumour-meningioma

Contact information

Type(s)
Scientific

Contact name
Dr Sarah Jefferies

Contact details
Addenbrooke's NHS Trust Oncology Centre
Box 193, Hills Road
Cambridge
United Kingdom
CB2 0QQ
-
sarah.jefferies@addenbrookes.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT00626730

Protocol serial number
5662; EORTC protocol 22042-26042

Study information

Scientific Title
Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma: a phase II and observation study

Study objectives
This study is looking at how effective radiotherapy after surgery can be at preventing the reoccurance of meningioma, a type of brain tumour.

The aims of this study are to see:
1. How long high dose radiotherapy stops the meningioma coming back for
2. How well people cope with the treatment
3. How well people having the treatment can carry out simple instructions and tasks afterwards

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Research Ethics Committee, 05/09/2008, ref: 08/H1102/43

Study design
Multicentre non-randomised interventional phase II treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Brain Tumour; Disease: Brain and Nervous System

Interventions
Simpson grade 1 - 3: 60 Gy to the CTV1, treatment duration 6 weeks
Simpson grade 4 - 5: 60 Gy to the CTV1 and then 10Gy boost to CTV2, treatment duration 7 weeks

Follow up on both arms: 1st follow up 6 weeks post last irradiation, 2nd follow up will be 6 months after trial entry, 3rd follow up at 12 months and yearly thereafter.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Three year progression free survival (PFS)
2. Acute and long term toxicity

Measured at baseline, during treatment, 6 weeks after end of radiotherapy (RT), 6 months after trial entry, 12 months after trial entry and then yearly. For both endpoints, the patients not having experienced the event(s) of interest are censored at the date of most recent follow-up.

Key secondary outcome(s))
Overall survival (OS), measured from date of entry to date of death, irrespective of the cause.

For both endpoints, the patients not having experienced the event(s) of interest are censored at the date of most recent follow-up.

Completion date
28/02/2011

Eligibility

Key inclusion criteria
1. Histologically confirmed newly diagnosed meningioma, including the following subtypes (atypical World Health Organisation [WHO] grade II meningioma greater than or equal to 4 mitosis per high-power field [HPF] or the presence of at least 3 of the following variables):
1.1. Cellularity
1.2. Architectural sheeting (i.e., patternless pattern)
1.3. Macronuclei cell formation
1.4. Small cell formation
1.5. Malignant WHO grade III meningioma
2. All locations allowed except for optic nerve sheets tumours
3. Complete or subtotal resection as assessed by the surgeon after verification with a post-operative magnetic resonance imaging (MRI) and according to Simpson guidelines
4. No neurofibromatosis type 2 (NF-2)
5. Female, aged 53 - 67 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
78

Key exclusion criteria
1. No optic nerve sheet tumours nor neurofibromatosis type II
2. No previous radiation therapy to the meninges or brain
3. No second malignancies

4. 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

Date of first enrolment
22/11/2008

Date of final enrolment
28/02/2011

Locations

Countries of recruitment
United Kingdom

England

Belgium

France

Germany

Italy

Netherlands

Spain

Switzerland

Study participating centre
Addenbrooke's NHS Trust Oncology Centre
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
European Organisation for Research and Treatment of Cancer (EORTC)

ROR
https://ror.org/034wxcc35

Funder(s)

Funder type
Research organisation

Funder Name
European Organisation for Research and Treatment of Cancer

Alternative Name(s)
EORTC

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	quality assurance results	30/01/2013	07/03/2019	Yes	No
Results article	results	01/08/2018	07/03/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			25/10/2022	No	Yes