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Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT00626730

Secondary identifying numbers

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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 measure
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.

Secondary outcome measures
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.

Overall study start date
22/11/2008

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

Age group
Adult

Sex

Female

Target number of participants
Planned sample size: 77

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
Belgium

England

France

Germany

Italy

Netherlands

Spain

Switzerland

United Kingdom

Study participating centre
Addenbrooke's NHS Trust Oncology Centre
Cambridge
United Kingdom
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Sponsor information

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

Sponsor details
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Sponsor type
Research organisation

Website
http://www.eortc.be

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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
Plain English results			25/10/2022	No	Yes