

Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma

Submission date 21/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

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 reoccurrence 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 sheath 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 sheath 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

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CB2 0QQ

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