

A phase III multi-centre randomised controlled trial to assess whether optimal supportive care alone (including dexamethasone) is as effective as optimal supportive care (including dexamethasone) plus whole brain radiotherapy in the treatment of patients with inoperable brain metastases from non-small cell lung cancer

Submission date 10/08/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/03/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-looking-at-the-treatment-of-lung-cancer-which-has-spread-to-the-brain>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00403065

Secondary identifying numbers

MRC LU24

Study information

Scientific Title

A phase III multi-centre randomised controlled trial to assess whether optimal supportive care alone (including dexamethasone) is as effective as optimal supportive care (including dexamethasone) plus whole brain radiotherapy in the treatment of patients with inoperable brain metastases from non-small cell lung cancer

Acronym

QUARTZ (Quality of Life After Radiotherapy and Steroids)

Study objectives

That optimal supportive care (including dexamethasone) alone is as effective as optimal supportive care (including dexamethasone) plus whole brain radiotherapy, in terms of patient-assessed quality-adjusted life-years in patients with non-small cell lung cancer (NSCLC) and inoperable brain metastases.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West Multicentre Research Ethics Committee, 22/09/2006, ref: 06/MRE08/55

Study design

Phase III 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Non-small cell lung cancer with inoperable brain metastases

Interventions

Optimal supportive care (OSC, including dexamethasone) alone versus OSC and whole brain radiotherapy (WBRT).

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Dexamethasone

Primary outcome measure

Quality-adjusted life-years. Follow-up is weekly until 12 weeks, then 4 weekly, until death.

Secondary outcome measures

1. Overall survival
2. Karnofsky Performance Status
3. Patient symptoms

Follow-up is weekly until 12 weeks, then 4 weekly, until death.

Overall study start date

02/03/2007

Completion date

31/05/2015

Eligibility**Key inclusion criteria**

1. Histologically or cytologically proven primary NSCLC
2. Computed tomography (CT)/magnetic resonance imaging (MRI) confirming brain metastases
3. Inoperable brain metastases as assessed by a lung cancer Multi-Disciplinary Team (MDT) or patients for whom surgery is deemed inappropriate
4. Clinician and patient uncertain of the role of whole brain radiotherapy (WBRT)
5. Patient able and willing to respond to questions in a weekly telephone assessment
6. Patient able and willing to give informed consent
7. Aged over 18 years
8. Baseline patient assessment form completed

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

534

Key exclusion criteria

Current exclusion criteria as of 14/01/2014:

1. Clinician and/or patient certain that WBRT will be of benefit
2. Clinician and/or patient certain that WBRT will not be of benefit
3. Previous or current illness, which has not been brought under control and/or is likely to interfere with protocol treatment or comparisons
4. Chemotherapy (last cycle) within 3 weeks prior to randomisation
5. Previous radiotherapy to the brain
6. Surgery for brain metastases within one month prior to randomisation

Previous exclusion criteria:

1. Clinician and/or patient certain that WBRT will be of benefit
2. Clinician and/or patient certain that WBRT will not be of benefit
3. Previous or current illness, which has not been brought under control and/or is likely to interfere with protocol treatment or comparisons
4. Estimated glomerular filtration rate (EGFR) inhibitors within one week prior to randomisation
5. Chemotherapy (last cycle) within one month prior to randomisation
6. Previous radiotherapy to the brain
7. Surgery for brain metastases within one month prior to randomisation

Date of first enrolment

02/03/2007

Date of final enrolment

31/08/2014

Locations**Countries of recruitment**

Australia

England

United Kingdom

Study participating centre

Newcastle General Hospital
Newcastle upon Tyne
United Kingdom
NE4 6BE

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

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2nd Floor
Stephenson House
158 -160 North Gower Street
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NW1 2DA
+44 (0)207 670 4625
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Sponsor type

Research organisation

Website

<http://www.centre-london.mrc.ac.uk>

ROR

<https://ror.org/03x94j517>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK) (ref: C17956/A6414)

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

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	results	01/03/2013		Yes	No
Results article	results	22/10/2016		Yes	No
Plain English results			24/03/2022	No	Yes