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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	[X] Prospectively registered [_] Protocol
Registration date 22/09/2006	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 24/03/2022	**Condition category** Cancer	[_] 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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00403065

Protocol serial number
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

Primary study design
Interventional

Study design
Phase III multi-centre randomised controlled trial

Study type(s)
Treatment

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

Key secondary outcome(s)
1. Overall survival
2. Karnofsky Performance Status
3. Patient symptoms
Follow-up is weekly until 12 weeks, then 4 weekly, until death.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

Australia

Study participating centre
Newcastle General Hospital
Newcastle upon Tyne
United Kingdom
NE4 6BE

Sponsor information

Organisation
Medical Research Council (MRC) (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, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

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

IPD sharing plan summary

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