

# 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

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

**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

### Study design

Phase III multi-centre randomised controlled trial

### Primary study design

Interventional

### 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?
<a href="#">Results article</a>	results	01/03/2013		Yes	No
<a href="#">Results article</a>	results	22/10/2016		Yes	No
<a href="#">Plain English results</a>			24/03/2022	No	Yes