

Impact of smoking cessation on multi-drug resistance in patients undergoing chemotherapy for non small cell lung cancer (NSCLC)

Submission date 29/09/2006	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/10/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0051160968

Study information

Scientific Title

Study objectives

The purpose of this study is to determine whether patients with non-small cell lung cancer should be advised to stop smoking during chemotherapy. The hypothesis is that cessation of smoking will reduce the resistance of these patients tumours to therapy. The study aims to use a nuclear medicine test known as Tc-99m MIBI imaging to compare changes in drug resistance in smokers undergoing chemotherapy for non-small cell lung cancer randomised to cessation or continuation of smoking. A reduction in PGP expression on cessation of smoking would suggest that patients would benefit from stopping smoking during chemotherapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Cancer: Non small cell lung cancer

Interventions

Patients: a pilot study will be performed comprising 18 smokers (at least 20/day) with non-small cell lung cancer who are to undergo chemotherapy. The study will provide preliminary data that will form the basis of an application for funding for subsequent larger trial.

Study Design: All patients will undergo biphasic Tc-99m MIBI imaging before chemotherapy. Patients will then be randomised to cessation or continuation of smoking. Tc-99m MIBI imaging will be repeated one week after the completion of the first cycle of chemotherapy.

Imaging: For each imaging study, patients will receive 600 MBq Tc-99m MIBI intravenously with 5 minute images acquired on a double-headed gamma camera at 15 minutes and 180 minutes. A region of interest will be drawn over the tumour on anterior and posterior images and geometric mean values of tumour activity will be determined. The MIBI wash-out will be determined from the ratio of tumour counts on early and late images. Initial (15 min) and residual (180 min) tumour uptake of MIBI will also be expressed as a target-to-background (TB) ratios by comparison with a mirror-image ROI placed over the opposite lung.

Statistical analysis: The mean changes in initial and residual tumour uptake and tumour MIBI washout rate before and after chemotherapy will be compared between patients who stopped smoking and those who continues using non-parametric tests. If the differences are not statistically significant, the data will be used for power analysis to determine the sample-size required for future studies.

As of March 2008: trial abandoned due to an inability to recruit patients who would continue smoking.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The study aims to use serial imaging with Tc-99m MIBI to compare changes in expression of PGP mediated multi-drug resistance in smokers undergoing chemotherapy for non-small cell lung cancer randomised to cessation or continuation of smoking. A reduction in PGP expression on cessation of smoking would suggest that patients would benefit from stopping smoking during chemotherapy.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/08/2005

Completion date

31/07/2006

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. 18 smokers (at least 20/day) with NSCLC will be included in the study.
2. Patients will be identified, approached and recruited by Dr Mitra (consultant oncologist) in the oncology clinic.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

18

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/08/2005

Date of final enrolment

31/07/2006

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Brighton & Sussex University Hospitals NHS Trust (RSCH)

Brighton

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Sponsor information**Organisation**

Sponsor details

The Department of Health, Richmond House, 79 Whitehall
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Sponsor type

Government

Website

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Funder(s)**Funder type**

Government

Funder Name

Brighton and Sussex University Hospitals NHS Trust (UK)

Funder Name

NHS R&D Support Funding

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration