ISRCTN48355604 https://doi.org/10.1186/ISRCTN48355604

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	[ ] Prospectively registered [ ] Protocol
Registration date 29/09/2006	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 17/10/2012	**Condition category** Cancer	[ ] Individual participant data [ ] 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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BN2 5BE

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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