ISRCTN27242710 https://doi.org/10.1186/ISRCTN27242710

A phase II trial of docetaxel in the treatment of elderly patients (aged 70 or over) with non-small cell lung cancer

Submission date 09/10/2007	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 14/01/2008	**Overall study status** Stopped	
Last Edited 01/08/2012	**Condition category** Cancer	

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Riyaz Shah

Contact details
Kent Oncology Centre
Maidstone Hospital
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NSCLC-DOCET_L_02602

Study information

Scientific Title

Acronym
ELTAX

Study hypothesis
To assess the efficacy of docetaxel (60 mg/m^2, on day one of every 21-day cycle [d1, q21]) as first line chemotherapy in elderly patients with advanced non-small cell lung cancer (NSCLC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
In progress through NRES, pending as of 14/01/2008.

Study design
Simon 2 stage MiniMax: this is a single arm (non-randomised) phase II trial with 2 stages

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Condition
Advanced stage non small cell lung cancer

Interventions
This is a single arm (non-randomised) phase II trial with 2 stages. The first stage will involve recruiting 31 patients. If there is evidence of activity then the trial will complete recruitment of a further 24 patients.

Patients will be treated with docetaxel 60 mg/m^2 intravenously (iv) once every 3 weeks for 4 - 6 cycles. Patients will be followed up until death.

Please note that as of 01/08/2012 this record was updated to show that the trial was stopped in 2009.

Intervention Type

Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Docetaxel

Primary outcome measure
Response rate, measured by RECIST criteria once all patients have completed protocol defined therapy.

Secondary outcome measures
1. Progression free survival, measured using the Kaplin Meier method
2. Overall survival, measured using the Kaplin Meier method
3. Survival in patients who received less than or equal to 2, greater than 2 but no more than 4 versus more than four 4 cycles of chemotherapy, measured using the Kaplin Meier method
4. Toxicity
5. Quality of life, measured using European Organisation for Research and Treatment of Cancer Quality of Life Questionnaires (EORTC QLQ-C30 and QLQ-LC13). Scoring will be performed using the EORTC QLQ-C30 scoring manual
6. Comparison of the use of second and third line therapies

Overall study start date
01/01/2008

Overall study end date
01/01/2009

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Participant inclusion criteria
1. Aged greater than or equal to 70 on the day of first treatment
2. Histologically or cytologically confirmed NSCLC
3. Any stage not suitable for surgery or radical radiotherapy
4. Radiologically evaluable disease (by Response Evaluation Criteria In Solid Tumours [RECIST] criteria) of at least one measurable lesion on chest X-ray (CXR) or computed tomography (CT)
5. Performance status World Health Organization (WHO) of 0, 1 or 2
6. Life expectancy greater than 12 weeks
7. Adequate haematological and biochemical function

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
55

Participant exclusion criteria
1. Prior chemotherapy (previous surgery and palliative radiotherapy are allowed)
2. Uncontrolled non-cancer systemic disease
3. Significant clinical or laboratory abnormalities
4. Concomitant or previous malignancy likely to interfere with treatment outcome
5. WHO performance status of worse than 2
6. Inadequate renal function
7. Inadequate bone marrow function

Recruitment start date
01/01/2008

Recruitment end date
01/01/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Kent Oncology Centre
Maidstone
United Kingdom
ME16 9QQ

Sponsor information

Organisation
Maidstone and Tunbridge Wells NHS Trust (UK)

Sponsor details
Research Management and Governance Centre
Kent and Medway Primary Care Trust
Ward Block, Preston Hall
Aylesford, Kent
Maidstone

England
United Kingdom
ME20 7NJ

Sponsor type
Hospital/treatment centre

Website
http://www.kentandmedway.nhs.uk/

ROR
https://ror.org/02yq33n72

Funder(s)

Funder type
Industry

Funder Name
Sanofi-Aventis Pharma (UK)

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