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

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

**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**
NSCLC-DOCET_L_02602

# Study information

## Scientific Title

## Acronym
ELTAX

## Study objectives
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

## Health condition(s) or problem(s) studied
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

### Completion date
01/01/2009

### Reason abandoned (if study stopped)
Objectives no longer viable

## Eligibility

### Key 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

### Key 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

### Date of first enrolment
01/01/2008

### Date of final enrolment
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