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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

Submission date
09/10/2007

Registration date
14/01/2008

Last Edited
01/08/2012

Recruitment status
Stopped

Overall study status
Stopped

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Protocol serial number
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.

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
Response rate, measured by RECIST criteria once all patients have completed protocol defined therapy.

Key secondary outcome(s)

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

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Maidstone and Tunbridge Wells NHS Trust (UK)

ROR
https://ror.org/02yq33n72

Funder(s)

Funder type
Industry

Funder Name
Sanofi-Aventis Pharma (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration