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Concomitant chemoradiotherapy for treatment of non-small cell lung cancer - the Conrad study

Submission date	Recruitment status	[_] Prospectively registered
28/04/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/05/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/01/2019	Cancer	

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
Norwegian Social Science Data Services no. 15175; UNN (PVO) no. 0147

Study information

Scientific Title
A randomised, multicentre phase III trial of combination chemotherapy +/- thoracic radiotherapy in the treatment of patients with stage III non-small cell lung cancer not eligible for radical therapy

Acronym
Conrad

Study objectives
That a combination of chemotherapy and thoracic radiation is superior to chemotherapy alone in the treatment of patients with stage III non-small cell lung cancer, non-eligible for radical therapy, with overall survival as primary endpoint.

Protocol can be found at: http://www.nlcg.no/uploads/conrad_protokoll.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Regional Ethical Review Board approved on the 19th July 2006
2. Norwegian Social Science Data Services approved on the 7th November 2006

Study design
Open randomised multicentre phase III trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non-small cell lung cancer

Interventions
The participants will be randomised to the following two arms:
Arm 1: Chemotherapy and thoracic radiation
Arm 2: Chemotherapy alone

Chemotherapy:
All patients will receive 4 cycles of identical regimes of chemotherapy: Oral vinorelbine tablets 60 mg/m^2 orally (per os) day 1 and 8 and intravenous carboplatin AUC = 5 (Calvert's formula) over one hour day 1. However, the doses will be adjusted according to age (patients age greater than 75 year will be given 75% of full dose from cure no.1) and haematological toxicity.

Schedule of radiation therapy:
Simulator planned, two opposing fields with fractionation 2.8 Gy x 15. The radiotherapy should start at the same time as or just after cycle number two. Cycle number three should be given three weeks after cycle number two.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Overall survival, followed-up for 52 weeks.

Key secondary outcome(s))
1. Health related quality of life, assessed by the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30) version 3.0 and the lung cancer specific module EORTC QLQ-LC13. The questionnaires will be sent to the patients every month during the treatment period and every second month after the treatment period for a total of 10 questionnaires completed per patient.
2. Time to progression, followed-up for 52 weeks
3. In field relapse, followed-up for 52 weeks
4. Drug related adverse event frequency and severity, followed-up for 52 weeks
5. Health economics, followed-up for 52 weeks

Completion date
15/11/2013

Eligibility

Key inclusion criteria
1. Chemo-naive patients with non-small cell lung cancer (NSCLC) locally advanced stage III, not candidates for radical radiotherapy and with no pleural effusion
2. Performance status (World Health Organization [WHO]) 0 - 2
3. Ability to understand oral and written study information
4. Both males and females, no age limit
5. S-creatinine less than 1.5 times upper reference limit, bilirubin and S-transaminase levels less than 2 times upper limits. Normal white blood-cell and platelet count.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Other active malignancies
2. Pregnancy or breast feeding

Date of first enrolment
15/11/2006

Date of final enrolment
15/11/2013

Locations

Countries of recruitment
Norway

Study participating centre
Oncology Department
Tromsø
Norway
9038

Sponsor information

Organisation
Pierre Fabre Pharma Norden AB (Sweden)

ROR
https://ror.org/04hdhz511

Funder(s)

Funder type
Industry

Funder Name
Regional Health Authorities (HELSE NORD) (Norway)

Funder Name
Pierre Fabre Pharma Norden AB (Sweden)

Funder Name
Please note that the Conrad study was initiated by the Norwegian Lung Cancer Group.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/09/2013	21/01/2019	Yes	No
Results article	results	01/06/2014	21/01/2019	Yes	No
Results article	results	01/05/2015	21/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes