STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: No drug
ACTIVE INGREDIENT: No drug

Study No: NIS-OSE-DUM-2010/1, NCT number NCT01139619
A retrospective, medical record study to investigate the current situation of biopsy testing in the Swedish inoperable Non Small Cell Lung Cancer patient population.

Developmental Phase: Observational study
Study Completion Date: 30 January 2013
Date of Report: 13 Dec 2013

OBJECTIVES:

Objectives of this study were to describe complications, the possibility of performing core needle lung biopsy, time to diagnosis, quality of samples and difference in outcome for lung cancer patients diagnosed in different ways.

METHODS:

Data was collected retrospectively from medical records at 3 Swedish hospitals. Eligible subjects were inoperable NSCLC patients with diagnosis of lung cancer between 2009-06-01 and 2010-05-31. Patients were included in consecutive order backwards from 2010-05-31. Data on first line treatment and status one year after diagnosis was collected. Data was primarily derived from medical records on the responsible pulmonology clinic at each site. Radiology- and Pathology clinics were consulted to enter or clarify data when needed.

RESULTS:

A total of 132 patients were included in the study. Mean age was 68 years and 48% of the patients were female. 13% of the patients were classified as non-smokers, 36% ex-smokers and 51% regular smokers. Bronchoscopy was performed in 79% of all patients, 42% had a biopsy by pulmonologist and 29% a CT-guided biopsy.

Complications were reported for 7 bronchoscopies (6% of all bronchoscopies), 1 biopsy performed by pulmonologist (2% of all) and 5 CT-guided biopsies (13% of all).

Data on predefined variables for a theoretical algoritm used to determine if core needle lung biopsy could be possible to perform was available for 58 patients. The predefined criterias were fulfilled by 9 patients (16%). Low Hb and/or anticoagulantia was reported for 4 of these 58 patients.

Transthoracic biopsy was reported as sampling method for diagnosis for 25 patients, median time to diagnosis 28 days. Bronchoscopy was reported for 63 patients, median time to diagnosis 10 days.

Out of the 96 patients who did not have an EGFR mutation test done, 8 had sufficient material for EGFR mutation test, in the opinion of a pathologist. 54 patients did not have sufficient material for testing and 34 were unknown.

Histopathology was reported as method used for diagnosis for 92 patients, cytology for 39 patients. For the Histopathology group the distribution was 53 deceased, 21 in progression and 18 was progression free after one year from diagnosis. In the Cytology group 25 were deceased, 6 in progression and 8 progressions free. One patient was not diagnosed by histopathology or cytology and was reported deceased after one year.

It was not possible to describe parameters that determine patients in high risk for complications following biopsy, or evaluate the risk of taking a core needle biopsy against the risk of a shorter survival.