Trial Description

Title

Clinical Research Platform Into Molecular Testing, Treatment and Outcome of Non-Small Cell Lung Carcinoma Patients

Trial Acronym

CRISP

URL of the trial

[---]*

Brief Summary in Lay Language

Open, non-interventional, prospective, multi-center clinical research platform with the main objective to assess molecular biomarker testing, treatment and outcome of patients with advanced or metastatic NSCLC in Germany

Brief Summary in Scientific Language

Thorough knowledge of the treatment reality, e.g. characteristics, diagnostic, treatment and outcome of unselected patients in real-life practice, is crucial to evaluate and improve the quality of care for patients with non-small cell lung cancer (NSCLC).

The purpose of CRISP is to set up a national clinical research platform to document uniform data on the molecular testing, treatment, course of disease in patients with NSCLC. A particular focus is on molecular biomarker testing before the start of first-line treatment of patients with advanced or metastatic NSCLC. The data shall be used to assess the current state of care and to develop recommendations concerning topics that could be improved.

PRO assessment will provide large-scale data on quality of life and anxiety/depression for real-life patients with NSCLC in routine practice. In addition, two questionnaires (concerning individual quality of life and patient-caregiver communication) will be validated in German patients with metastatic NSCLC.

Furthermore CRISP will set up a decentralized clinically annotated tissue repository for future collaborative, investigational scientific biomarker testing.

Organizational Data

- DRKS-ID: DRKS00010126
- Date of Registration in DRKS: 2016/07/06
- Date of Registration in Partner Registry or other Primary Registry: 2015/12/02
DRKS-ID: **DRKS00010126**  
Date of Registration in DRKS: **2016/07/06**  
Date of Registration in Partner Registry or other Primary Registry: **2015/12/02**  

- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**  
- Ethics Approval/Approval of the Ethics Committee: **Approved**  
- (leading) Ethics Committee Nr.: **F-2015-052#A1 , Ethik-Kommission bei der Landesärztekammer Baden-Württemberg**  

### Secondary IDs

- Primary Registry-ID: **NCT02622581 (ClinicalTrials.gov)**  
- Sponsor-ID: **AIO-TRK-0315 (AIO-Studien-gGmbH)**  

### Health condition or Problem studied

- Free text: **Metastatic Non-small Cell Lung Cancer (NSCLC)**  
- ICD10: **C34 - Malignant neoplasm of bronchus and lung**  

### Interventions/Observational Groups

- **Arm 1:** Patient with non-small cell lung cancer (NSCLC) documentation of real-world date regarding treatment reality, molecular testing and quality of life  

### Characteristics

- Study Type: **Non-interventional**  
- Study Type Non-Interventional: **Observational study**  
- Allocation: **Other**  
- Blinding: [---]*  
- Who is blinded: [---]*  
- Control: **Other**  
- Purpose: **Health care system**  
- Assignment: **Other**  
- Phase: [---]*  
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*
To assess molecular biomarker testing, treatment and outcome of patients with NSCLC in Germany, in particular:

- To collect data on the frequency, methodology and results of molecular biomarker testing before first-line and later-line treatment
- To describe types of surgeries, systemic treatments, radiochemotherapies, radiation therapies and sequential treatments thereof applied in real-life practice
- To assess effectiveness of treatments in regards to response rate, progression-free survival and overall survival
- To describe physician-reported factors affecting treatment decision making besides biomarker profiling
- To collect key data on specific supportive therapies
- To investigate changes in diagnostics, treatment or outcome during the course of the project
- To evaluate patient-reported outcomes concerning (1) general health-related and individual quality of life (QoL), (2) physical and psychological well-being, (3) anxiety and depression, (4) patient-caregiver communication

Secondary Outcome

none

Countries of recruitment

- DE Germany

Locations of Recruitment

- Medical Center Pius-Hospital, Oldenburg
- other mehr als 160 weitere Zentren/ more than additional 160 sites, [---]*

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2015/12/31
- Target Sample Size: 5000
- Monocenter/Multicenter trial: Multicenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
Gender: Both, male and female

- Minimum Age: 18 Years
- Maximum Age: no maximum age

### Additional Inclusion Criteria

1. Patients who meet all of the following criteria are eligible for the project:
   - Histologically confirmed non-small cell lung cancer (NSCLC)
2. Informed consent no later than four weeks after start of first-line treatment
3. Age ≥ 18 years
4. Able to understand and willing to sign written Informed Consent and to complete patient-reported-outcome assessment instruments
5. Main project:
   - Stage IV, IIIC or stage IIIB (UICC8) if patient is ineligible for curative surgery and/or radiochemotherapy
   - Systemic therapy
   In the main project it is strongly recommended that patients’ tumor samples are tested for EGFR mutation in exons 18-21, ALK rearrangement and ROS1 rearrangement as well as PD-L1 expression by a certified laboratory before the start of first-line treatment.
6. Satellite Stage II/III:
   - Stage II, stage IIA or stage IIIB (UICC8) if patient is eligible for curative surgery and/or radiochemotherapy
   - Systemic (chemo)therapy and/or radiation therapy and/or surgery

### Exclusion Criteria

none

### Addresses

- **Primary Sponsor**
  
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Sources of Monetary or Material Support

- Commercial (pharmaceutical industry, medical engineering industry, etc.)

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Status

- Recruitment Status: Recruiting ongoing
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

- Further trial documents AIO - Working Group for Medical Oncology from the German Cancer Society

* This entry means the parameter is not applicable or has not been set.
*** This entry means that data is not displayed due to insufficient data privacy clearing.