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A clinical registry for longitudinal data on the clinical, psychosocial, and economic impact of lung cancer treatment in Italy

Submission date 02/09/2022	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/10/2022	**Overall study status** Ongoing	
Last Edited 03/12/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Most lung cancer cases correspond to non-small cell lung cancer (NSCLC), while small cell cancer represents the minority of cases. To date, a limited percentage of NSCLC cases are diagnosed in the early stage (in which patients are potential candidates for surgery, followed by chemotherapy to reduce the risk of recurrence) or in the locally advanced stage (in which the treatment is based on the use of chemotherapy, radiotherapy and, upon their completion, immunotherapy). The therapeutic strategy in patients with advanced NSCLC has changed in recent years. Therefore, we propose developing a web-based registry for collecting longitudinal data on the clinical, psychosocial and economic impact of lung cancer treatment in Italy.

Who can participate?
Patients suffering from lung cancer and candidates for surgical intervention

What does the study involve?
Collection of clinical data to be entered into a national database.

What are the possible benefits and risks of participating?
No risk for the participants

Where is the study run from?
University of L'Aquila (Italy)

When is the study starting and how long is it expected to run for?
September 2022 to December 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)
NCT05851755

Protocol serial number
hf65sh

Study information

Scientific Title
Lung Cancer Observational Study

Acronym
LUCENT

Study objectives
Most lung cancer cases correspond to non-small cell lung cancer (NSCLC), while small cell cancer represents the minority of cases. To date, a limited percentage of NSCLC cases are diagnosed in the early stage (in which patients are potential candidates for surgery, possibly followed by chemotherapy to reduce the risk of recurrence) or in the locally advanced stage (in which the treatment is based on the use of chemotherapy, radiotherapy and possibly, upon their completion, immunotherapy). The therapeutic strategy in patients with advanced NSCLC has changed in recent years. Until about ten years ago, chemotherapy was the only option available, however, characterised by limited effectiveness. In recent years, the two crucial therapeutic "revolutions" that we have witnessed in medical oncology (molecularly targeted drugs first and then immunotherapy) have played an essential role in treating these patients. Some molecularly targeted drugs (primarily Epidermal Growth Factor Receptor [EGFR] inhibitors and then drugs directed against other molecular alterations) are superior to chemotherapy as a first choice treatment, limited to cases in which the tumour has those specific molecular alterations. Molecular analyses aimed at identifying these alterations on the tumour tissue represent a fundamental part of the diagnosis, which precedes the best treatment choice for each patient. In the next few years, we will plausibly see the continuation of the aforementioned therapeutic "revolution" with the availability of new molecularly targeted drugs, which will not only increase the therapeutic possibilities to be used in sequence after the failure of those already available today but which in some cases they will allow a "targeted" treatment in the presence of alterations molecular drugs for which no target drugs were available in clinical practice until now. Immunotherapy first established itself (about five years ago) as an effective treatment for patients who had already failed chemotherapy. Subsequently, it proved to be superior to chemotherapy as a treatment of the first choice in cases characterised by high expression of the PD-L1 marker. Finally, in recent years, significant results have been obtained with the combination of chemo and immunotherapy, even in cases characterised by low or absent PD-L1 expression. It is conceivable that in the coming years, based on a series of clinical trials recently conducted or still in progress, innovative drugs (targeted therapies and immunotherapy) will also gain an essential role in the treatment of early stages, used before surgery or after surgery, in order to reduce the risk of disease recurrence and hopefully increase the chances of recovery. The 5-year survival figure (16% in men and 23% in women), which places lung cancer at the bottom of this unfortunate ranking, reminds us that, despite the critical progress made in recent years, the way to go is still very long [AIOM, I numeri del Cancro in Italia 2021].
Globally, there is an increasing trend to use real-world data (RWD) to inform decision-making in healthcare, and patient registries are regarded as a typical example of RWD. A patient registry

can be defined as “an organised system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes [GliklichRE, DreyerNA. Registries for Evaluating Patient Outcomes: A User’s Guide (2nd ed.). Rockville, MD: Agency for Healthcare Research and Quality, 2010.]. Whilst regulatory agencies can require real-world data collection for post-marketing surveillance, and risk assessment, payers and reimbursement agencies are consistently considering real-world evidence to make or revise their recommendations. To this end, the information collected in patient registries can extend from appropriate treatment strategies to effectiveness and cost-effectiveness in real-world clinical practice.
Furthermore, achieving and maintaining optimal well-being and health-related quality of life (HRQoL) has become an essential objective of current cancer treatment, rehabilitation, and aftercare across the whole cancer continuum. The availability of patient-reported outcomes (PROs) is critical for achieving these goals. Over the past, patient registries have provided clinicians and researchers with a wealth of clinical data (e.g., stage and primary treatment) on cancer patients. However, data on PROs have not been routinely available. PROs were collected using paper-and-pencil questionnaires, with suboptimal response rates, costs and overall efficiency of the process. Online administration of questionnaires has several advantages compared to paper-and-pencil questionnaires, including convenience for the participant, potentially significant cost savings, efficiency in data collection, and high quality of the data. Therefore, we propose developing a web-based registry for collecting longitudinal data on the clinical, psychosocial and economic impact of lung cancer treatment in Italy.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/04/2023, Technical Scientific Secretariat IRCCS ISMETT Sectional Ethics Committee (Clinical Headquarters via E. Tricomi 5, Palermo, 90127, Italy; +39 091 21 92 111; not@available.com), ref: IRRB/04/23

Study design
We propose developing a web-based registry for collecting longitudinal data on the clinical, psychosocial, and economic impact of lung cancer treatment in Italy.

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Lung cancer

Interventions
Current interventions as of 05/04/2024:
LUCENT is a web-based registry developed to facilitate data collection on several different outcomes of lung cancer patients diagnosed in the early stage in Italy. The registry can be used simultaneously for multiple studies with other purposes.

Data from the participant will be collected inside a database until 31/12/2025. The follow-up of each patient will be done yearly.

The main objectives of LUCENT are to generate data relevant to:
• Performance assessment – through the development of national performance benchmarks based on the analysis of (risk-adjusted) outcomes and processes of care indicators (e.g., How does individual centre X compare to the national benchmark in terms of length of stay for a certain subgroup of patients?);
• Economic impact assessment of innovative technologies or treatment pathways (e.g., Do different surgical medical devices influence healthcare resource utilisations for a single episode of hospitalisation?)
• Psychosocial impact assessment of innovative technologies or treatment pathways (for example, minimally invasive surgery) (e.g., Do new targeted treatments have a beneficial or adverse impact on PROs?)

Previous interventions:
ILCAR is a web-based registry developed to facilitate data collection on several different outcomes of lung cancer patients diagnosed in the early stage in Italy. The registry can be used simultaneously for multiple studies with other purposes.

Data from the participant will be collected inside a database until 31/12/2025. The follow-up of each patient will be done yearly.

The main objectives of ILCAR are to generate data relevant to:
• Performance assessment – through the development of national performance benchmarks based on the analysis of (risk-adjusted) outcomes and processes of care indicators (e.g., How does individual centre X compare to the national benchmark in terms of length of stay for a certain subgroup of patients?);
• Economic impact assessment of innovative technologies or treatment pathways (e.g., Do different surgical medical devices influence healthcare resource utilisations for a single episode of hospitalisation?)
• Psychosocial impact assessment of innovative technologies or treatment pathways (for example, minimally invasive surgery) (e.g., Do new targeted treatments have a beneficial or adverse impact on PROs?)

Intervention Type
Other

Primary outcome(s)
Data will be entered into the registry at the time of patient follow-up, which is done yearly:
1. EuroQol-5D
2. Current smoking habit
3. Presence or absence of co-morbidites
4. BMI (kg/m²)
5. Lung function:
5.1. Spirometry - FEV1%, FVC%, DLCO/VA%
5.2. 6 minute walking test
5.3. Lung scintigraphy
5.4. Cardiopulmonary exercise testing
6. Cancer staging - cTNM, pTNM
7. Other diagnostic tests:

7.1. Bronchoscopy
7.2. FNAB
7.3. Mediastinoscopy
7.4. EBUS
7.5. EUS
8. Treatment history (chemotherapy, radiotherapy, surgery)
9. Progression of disease

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Age >18 years
2. Patients suffering from lung cancer candidates for surgical intervention
3. Signature of informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
1000

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/03/2023

Date of final enrolment
31/12/2028

Locations

Countries of recruitment
Italy

Study participating centre
University of L'Aquila
Italy
67100

Study participating centre
IEO, European Institute of Oncology IRCCS
Italy
20141

Study participating centre
University of Pisa
Italy
56121

Study participating centre
University of Bologna
Italy
40121

Study participating centre
Bolzano Regional Hospital
Italy
39100

Study participating centre
University of Florence
Italy
50100

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Italy
00100

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ISMETT
Italy
90121

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46100

Sponsor information

Organisation
University of L'Aquila

ROR
https://ror.org/01j9p1r26

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request
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IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/10/2024	11/10/2024	Yes	No
Protocol file			28/09/2022	No	No