Tumour Lysis Syndrome Associated with Lenvatinib: an Investigator-Initiated, Retrospective Observational Post-Authorisation Safety Study (TELSTAR)

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Study Planned

Administrative details

EU PAS number

EUPAS1000000977

Study ID

1000000977

DARWIN EU® study

No

Study countries

☐ Portugal

Study status

Planned

Contact details

Study institution contact

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Study timelines

Date when funding contract was signed

Planned: 15/05/2026

Study start date

Planned: 15/05/2026

Date of final study report

Planned: 01/03/2027

Sources of funding

- No external funding

Study protocol

Protocolo Lenvatinib.pdf (652.64 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Retrospective, single-centre observational cohort PASS using real-world EHR data to estimate the incidence of tumour lysis syndrome in adults treated with lenvatinib, with descriptive subgroup analyses and pharmacovigilance reporting.

Main study objective:

To estimate the incidence proportion of TLS, including both laboratory TLS and clinical TLS,
defined according to Cairo–Bishop criteria, among patients treated with lenvatinib at ULSSJ during the
study period

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

LENVIMA

KISPLYX

Study drug International non-proprietary name (INN) or common name

LENVATINIB

Anatomical Therapeutic Chemical (ATC) code

(L01EX08) lenvatinib

lenvatinib

Medical condition to be studied

Tumour lysis syndrome

Population studied

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Study design details

Setting

This single-centre study is conducted at ULS São João (Porto, Portugal) using routinely collected electronic health record and pharmacy data. The study population includes all adult patients (≥18 years) treated with lenvatinib for any oncologic indication between 28 May 2015 and 30 November 2025. Patients are identified through hospital pharmacy dispensing records and cross-checked with prescribing and oncology consultation systems.

Inclusion requires documented lenvatinib exposure and availability of baseline and on-treatment laboratory data sufficient to assess tumour lysis syndrome (TLS). Patients enrolled in interventional trials with lenvatinib or lacking adequate laboratory data are excluded from the evaluable cohort (though recorded for coverage assessment).

The study follows a single exposed cohort (no external comparator), with follow-up from treatment initiation (index date) until treatment discontinuation or last recorded contact. Subgroup analyses are planned according to clinically relevant variables, including treatment indication, baseline renal function, tumour burden (e.g. LDH), and combination therapy (e.g. with pembrolizumab).

Comparators

The study uses a single exposed cohort (lenvatinib-treated patients) without an external comparator group.

Outcomes

The primary outcome is the incidence proportion of tumour lysis syndrome (TLS) among patients treated with lenvatinib, defined according to Cairo–Bishop criteria and including both:
Laboratory TLS (LTLS)
Clinical TLS (CTLS)

Secondary outcomes include:
Clinical characterization of TLS cases (e.g. tumour type, renal function, tumour burden)
Severity grading (CTCAE v5.0)
Causality assessment (WHO-UMC)
Clinical outcomes (recovery, sequelae, death)

Subgroup incidence estimates (e.g. by indication, renal function, combination therapy)

Data analysis plan

The primary analysis will estimate the incidence proportion of tumour lysis syndrome (TLS) among evaluable lenvatinib-exposed patients, calculated as the number of patients with at least one TLS event during treatment divided by the number of evaluable exposed patients. Exact 95% binomial confidence intervals (Clopper–Pearson) will be calculated.

Secondary analyses will estimate incidence separately for laboratory TLS (LTLS) and clinical TLS (CTLS), and will also describe laboratory data coverage using all exposed patients as the denominator. Exploratory subgroup analyses will be performed according to clinically relevant variables such as indication, baseline renal function, LDH, and combination therapy. These comparisons will be presented descriptively using risk ratios with 95% confidence intervals and assessed with Fisher’s exact test. No imputation of missing data is planned; exclusions from the evaluable cohort and reasons for missingness will be summarized. All analyses will be performed in R (version 4.3 or higher)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Not applicable