Identification of cases and estimate of direct costs of unresectable and advanced cutaneous squamous cell carcinoma: real-world data from a large Italian database

First published: 05/06/2024

Last updated: 05/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS1000000152

Study ID

1000000152

DARWIN EU® study

No

Study countries

Italy

Study description

Observational retrospective and noninterventional study that, through administrative data from the Fondazione ReS database, has assessed the prevalence of unresectable and advanced (u/a) cSCC and calculated healthcare costs charged to the Italian National Health Service (SSN). The data source is derived from anonymized healthcare administrative databases owned by the Italian Regional Health Facilities and analysed by Fondazione ReS under a specific agreement and in compliance with European privacy rules. Patients with u/a cSCC in 2015 were identified through a step-by-step strategy: the 1st step was a diagnosis (ICD-9-CM code) of ‘other malignant neoplasm; the 2nd step was diagnosis of metastasis associated with an nonmelanoma skin cancer diagnosis, or by chemotherapy/radiotherapy supplies or prescriptions of antineoplastics/immunostimulants in the absence of a diagnosis of another neoplasm of the skin’: the 3rd step was the exclusion of patients receiving vismodegib, which is labelled for the treatment of basal cell carcinoma; the 4rth and last step was the exclusion of patients experiencing surgical excision (in hospital or ambulatory setting) within 1 year from the diagnosis of advanced cSCC, to to identify unresectable cases. A 1-year follow-up was considered to collect data on healthcare utilization and related costs charged to the SSN.

Study status

Finalised

Research institutions and networks

Institutions

Fondazione ReS (Ricerca e Salute), CINECA partner

Italy

First published: 05/07/2017

Last updated: 01/10/2025

Institution | Not-for-profit | ENCePP partner

Contact details

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Study timelines

Date when funding contract was signed

Actual: 08/01/2019

Study start date

Actual: 08/02/2019

Date of final study report

Actual: 08/05/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

This study was partially supported by and unrestricted grant from Sanofi.

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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Main study objective:

To assess the prevalence of unresectable and advanced (u/a) cSCC and to calculate healthcare costs charged to the Italian National Health Service.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Squamous cell carcinoma

Additional medical condition(s)

Advanced cutaneous squamous cell carcinoma

Study design details

Setting

Inpatient and outpatient settings

Summary results

This real-world study identified patients affected by u/a cSCC and estimated their healthcare costs, filling an information gap. The comparison of demographic data for our cohort with ad hoc information collected by a retrospective study,7 revealed an exact overlapping of sex distribution (67% men) and age (median 78 years) for cSCC cases. An additional important result of our study was the calculation of 1-year direct costs generated by patients affected by u/a cSCC and how these costs compared with those relating to the whole group of advanced cSCCs. In spite of the small number, each of these individuals cost more than €10 000 annually. This finding was unique as most health economic analyses do not differentiate between BCC and cSCC.

Documents

Study publications

Identification of cases and estimate of direct costs of unresectable and advanc…

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 source(s)

Database of Fondazione ReS

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes