INVESTIGATING SECULAR TRENDS IN THE SURVIVAL OF MELANOMA PATIENTS IN ENGLAND

First published: 28/06/2019

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Study Planned

Administrative details

EU PAS number

EUPAS30299

Study ID

33317

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This is an observational cohort study of patients diagnosed with malignant melanoma using cancer registration data from Pubic Health England (PHE). Our study aims to provide a detailed evaluation of melanoma survival over time in England. As previous studies have shown that melanoma survival varies significantly according to patient demographic characteristics, and particularly socioeconomic status we will also evaluate whether any observed changes over time vary within different subgroups, specifically disease stage and SES. Patients aged 18 years and above who are diagnosed with malignant melanoma of any stage from 1 January 1985 to 31 December 2015 will be identified from English Cancer Registry data held by Public Health England (PHE). The study period will span from 1 January 1985 until the latest available data (currently projected to be 31 December 2016). We will use the existing cancer registration data from PHE. The cancer registration dataset includes data on demographics, characteristics of the tumour, patients' vitality status and basic information regarding the treatment received.We will analyse the data to describe patient characteristics and calculate time to death. We will also calculate a measure called 'relative survival', which is an estimate of how the survival among cancer patients compares to that in the general population. This is valuable because not all patients who die may die due to their cancer, and this statistictakes that into account.

Study status

Planned

Research institutions and networks

Institutions

Evidera

United Kingdom

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Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Beth Nordstrom

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/11/2018

Actual: 12/11/2018

Study start date
Planned: 01/08/2019

Date of final study report
Planned: 30/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol Myers Squibb Pharmaceuticals Ltd

Study protocol

ODR_PHE_Cancer_Protocol_v1.0.pdf(240.38 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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

1. Describe the demographic and clinical characteristics of patients diagnosed with malignant melanoma 2. Describe one-year overall and net survival over time among malignant melanoma patients, and among subgroups of interest (disease stage and socioeconomic status)3. Model changes in survival over time among these patients4. Assess changes in survival within subgroups of interest

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Malignant melanoma

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

426188

Study design details

Outcomes

The primary outcomes of interest in this study are overall survival and relative survival. These will be assessed from the day after index until the last day of available data (during follow-up).

Data analysis plan

The demographic and clinical characteristics of the overall malignant melanoma cohort will be summarized using descriptive statistics. The non-parametric KM method will be used to estimate one-year OS for the overall study cohort and within each subgroup of interest, stratified by calendar year of diagnosis. Relative survival will be calculated as the ratio of overall survival for malignant melanoma patients during the one-year period following index date to the overall survival among a comparable cancer free population over the same one-year period. Trends in OS will be modeled using multivariable Cox proportional hazards models.Trends in relative survival will be modeled using generalized linear models using a Poisson assumption for the observed number of death.

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)

Disease registry

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

No