Gender Difference in sidE eFfects of ImmuNotherapy: a possible clue to optimize cancEr tReatment (G-DEFINER)

First published: 13/06/2020

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Study Ongoing

Administrative details

EU PAS number

EUPAS31282

Study ID

44938

DARWIN EU® study

No

Study countries

Ireland

Italy

Norway

Sweden

Study description

The study is a multicenter prospective observational study aimed at investigating sex and gender differences in the immune-related adverse events (irAEs) development in relation to clinical factors and genetic, immunological and hormonal profiles in patients with melanoma, lung, head and neck, urogenital, breast cancer treated with immunocheckpoint inhibitors (ICI). Exploring the irAEs occurrence in a real world context will be more easily translated in a ready-to-use personalized approach to irAEs timely diagnosis and treatment.

Study status

Ongoing

Research institutions and networks

Institutions

Fondazione IRCCS Istituto Nazionale dei Tumori

First published: 01/02/2024

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Institution

Karolinska University Hospital

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Institution

Oslo University Hospital

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

Dublin City University - St Vincent’s University Hospital Dublin, Ireland, Karolinska University Hospital Stockholm, Sweden, Oslo University Hospital Oslo, Norway

Contact details

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Study contact

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Primary lead investigator

Rosalba Miceli

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 19/02/2019

Study start date
Planned: 15/06/2020

Actual: 25/06/2020

Date of final study report
Planned: 28/02/2023

Sources of funding

- EU institutional research programme

More details on funding

Horizon 2020 GENDERNET PLUS ERANET

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:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The study aim is to investigate the differences between sex and gender in the immune-related adverse events development associated with immune checkpoint inhibitors reatmtent.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Breast cancer

Malignant melanoma

Additional medical condition(s)

Melanoma, lung, head and neck, urogenital, breast cancer and, in addition, other solid tumors characterized by the presence of microsatellite instability (MSI-high), treated with immunocheckpoint inhibitors (ICI) irrespective of treatment schedule. It is possible to include patients treated with Immunotherapy in a compassionate use setting.

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

400

Study design details

Outcomes

- To estimate and compare the immunorelated adverse events incidence in female and male patients, and estimate the incidence according to different clinical features and gender dimensions (behavioral and psychosocial differences associated with being female or male). - To estimate and compare the immunorelated adverse events incidence in pre- and postmenopausal women.

Data analysis plan

The incidence of first severe irAEs of any type will be estimated in F and M as a proportion of patients developing the event respect to the total number of patients at risk. The main comparison F vs M will be performed by estimating the odds ratio (OR) in a univariable logistic model, F/M unbalance for different clinical and gender-related characteristics will be taken into account using the “matching weight” (MW) method (applying the propensity score methodology). IrAE incidence will also be estimated according to irAE type and grade, tumor site, ICI treatment, patients’ age and gender-based characteristics by sex

groups. Logistic models using MW and including the interaction between sex and the different clinical features will be fitted to estimate OR according to different feature categories or values.

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)

Other

Data sources (types), other

Prospective patient-based data collection

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