Evaluation of potential predictive diagnostic methods for specifity, distribution and relevance of immune checkpoint proteins (EPPIC)

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37780

EU PAS number

EUPAS37779

Study ID

37780

DARWIN EU® study

No

Study countries

Germany

Study description

The aim of this study is the establishment of reliable and robust test methods for evaluation of immune checkpoint proteins in tumor tissues to predict efficiacy of targeted therapeutic strategies. We focus on cancers of the upper gastrointestinal tract obtained from surgical specimens without further or additional interventions.

Study status

Ongoing

Research institutions and networks

Institutions

University Hospital of Cologne

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

Institute of Pathology

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Alexander Quaas

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/10/2020

Actual: 27/10/2020

Study start date

Planned: 27/10/2020

Actual: 27/10/2020

Date of final study report

Planned: 27/10/2025

Sources of funding

- Other

More details on funding

Institute of Pathology, University Hospital of Cologne

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:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The main objective of the study is to establish a reliable and robust test method for immune checkpoint expression in cancer tissues to predict therapeutic Response.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Oesophageal carcinoma

Gastric cancer

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

2000

Study design details

Data analysis plan

The data analysis plan includes testing the reliability of immunohistochemical protein expression of cancer tissue considering correlation with expression on gene level and, in correlation to clinical follow up data, potential prediction of therapeutic response.

Data management

Data sources

Data sources (types)

Disease registry

Electronic healthcare records (EHR)

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