PATIENT REGISTRY

The Use of Genomic Testing and the Resulting Medical Decisions According to Target Identification

Protocol Number: AGMT_NGS

Coordinating Investigator: R. Greil[1, 2]

[1] 3rd Medical Department, Paracelsus Medical University Salzburg; [2] Salzburg Cancer Research Institute

Protocol Synopsis:

Indication: Patients for which broad genomic profiling is indicated as assessed by the medical need

Planned sample size: 500 patients

Status: 4 patients ([1]PMU Salzburg), as of March 2017

Design: retrospective and prospective, multicenter, non-interventional, observational

Duration: Q1 2017 - Q4 2019

Objectives:

The goal of this registry is to landscape the clinical practice of molecular profiling in Austrian cancer patients with focus on identification of methods used, evaluation when the tests are performed in the course of the disease, and definition of the impact of the test result on the subsequent treatment decision.

Rationale:

In the situation of enormous possible beneficial options for patients, health care systems, researchers and companies and the simultaneously present high number of uncertainties, the establishment of an independent registry for patients undergoing any type of comprehensive genomic profiling offers many advantages.

There is no evidence available about which molecular profiling methods are currently used for cancer patients in Austrian clinical practice. The construction of the registry proposed as a completely independent research endeavor, will be helpful for scientific evaluation and the establishment of highly credible data.

The registry proposes to cover the time period from the years 2016 to 2019, which will allow for assessment of both the current and emerging landscape of genomic/molecular testing practice in Austria and effect of molecular profiling on patient care and outcome.

Design:

This registry is designed as multicenter non-interventional (observational) cohort of oncology patients who received or plan to receive comprehensive genomic testing. Patient medical, testing and treatment information will be obtained through extraction of data from existing patient medical charts. Longitudinal follow-up data, including survival and tumor progression, will also be extracted from patient medical charts. This patient follow-up data will be obtained until patient death or loss to follow-up.

The registry will be made available for all disciplines and physicians caring for cancer patients. Indications for genomic testing are exclusively driven by the medical need. Physicians are free to use any type of genomic test available at their hospital or from any company. The decision to use comprehensive genomic testing must be clearly separated from the decision to include the patient in the registry.

Inclusion Criteria:

This registry will include cancer patients for which broad genomic profiling is indicated, for example:

- cancer with high mutational load and suspicion of regular or frequent formation of neoantigens
  - skin, lung, stomach, esophagus, colorectum, bladder, uterus, cervix, liver, head and neck, kidney, breast
  - lymphoma B-cell
- any other neoplastic disease where molecular targeting is performed but treatment fails
- cancer of unknown primary origin (CUP)

Further inclusion criteria:

- planned or already carried out comprehensive genomic testing as of Jan 1, 2016
- Signed written informed consent, age 18 years or over

Note: This registry will not initially register patients who are tested for only 1-5 mutations by conventional means, but patients undergoing genomic profiling based on NGS.

Objectives:

PRIMARY OBJECTIVES:

To describe the distribution and types of:

- molecular profiling methods used in the Austrian registry centres
- cancer, for which comprehensive molecular profiling is used
- the timing of molecular profiling in relation to stage of the disease (e.g. at diagnosis, after surgery, radiation therapy, after first/second/third/late line)

SECONDARY OBJECTIVES:

- To describe targets identified
- To describe tests used and quality standards
- To evaluate development of methods used over time
- To describe treatment decisions
- To describe outcome of treatment in patients receiving therapy in concordance with the test result

An academic registry

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