Horizon Europe Call for Partners

Call: Research and Innovation actions supporting the implementation of the Mission on Cancer (HORIZON-MISS-2021-CANCER-02)
Topic: Develop new methods and technologies for cancer screening and early detection
Topic ID: HORIZON-MISS-2021-CANCER-02-01
Deadline: 26 April 2022

Project idea

- ***miRNAs validation in Testicular Cancer to personalize prognostic and therapy***

Prospective validation of miRNAs (RNA sequencing) as prognostic and predictive biomarkers in all stages of Testicular Cancer in a large-scale population.

Project proposal, scope and objectives

The aim of the project is to clinically validate at large-scale the diagnostic and prognostic accuracy of the miR-371a-3p cluster in patients with Testicular Cancer and their role in the personalization of the treatment of patients with Testicular Cancer, whether in early stage or in metastatic disease.

Testicular cancer is a rare disease that affects 3 to 10 new cases per 100.000 males /year, most of them Adolescent and Young Adults (AYAs). Its incidence is increasing in developed countries and its impact is high in the social, professional, and familiar environment.

Although 70% of patients present in an early stage and exhibit an extremely high cure rate the present available biomarkers, AFP and β-hCG, have a low accuracy and predictive values and they are neither predictive nor prognostic. As such they are suboptimal to tailor treatment or monitor response, either in adjuvant or metastatic setting.

Micro RNAS (miRs), have been proposed as potential biomarkers with very high specificity in several cancers. They are non-coding RNAs playing a key role in the intra and intercellular communication that can be determined by high-throughput RNA sequencing methods.

From the several miR clusters involved in testicular Cancer development and progression the miR-371a-3p cluster exhibits a considerable higher accuracy and predictive ability than the biomarkers at use. It predicts recurrence in earlier stages, monitors response to chemotherapy in metastatic setting and acts as a prognosticator for the detection of viable cancer in the post-chemotherapy residual mass. Preliminary studies have shown a high diagnostic and predictive performance for this mR cluster in several testicular cancer clinical scenarios.

Major problems that prevent the incorporation of the miR-371a-3p in the early diagnostic and in the detection and monitoring of Testicular cancer is the lack of validation at large scale and of a standard technology easily available for generalization of use.

The project aims to prospectively validate the diagnostic and prognostic accuracy of miR-371a-3p cluster in a wide sample of patients with (or suspicion) Testicular cancer. The sample population will include individuals with suspicion or confirmation of testicular cancer in all possible clinical situations, from diagnostic to recurrent and metastatic disease and in any possible scenario through the process of care of early or metastatic TC. If the high accuracy of the molecular marker is confirmed as a second part of the project is the assessment as a screening test in the population at risk.

Besides the early detection, there important medical and societal benefits of the project. Firstly, selection of patients in early stage that should receive adjuvant treatment; secondly the early selection of those metastatic patients that will be non-responders to chemotherapy and require either other schedules or drug switch; thirdly the selection of those metastatic patients with post-chemotherapy residual masses that require excisional surgery. Ultimately the personalization of the treatment will lead to minimize systemic treatment and/or extended surgery and to minimize the risk of second chemo/radiation induced cancers, very well phenomenon in this population with a long-life expectancy. As a long-term benefit if the present project shows positive outcome, the new molecular marker reunites the characteristics to be tested in screening programs in the population at risk of testicular cancer, namely those males with features of testicular dysgenesis syndrome.

Expertise offered

Medipol Mega Hospital provide medical expertise in the treatment of patients with Testicular Cancer in all stages of the disease. Istanbul Medipol University has genomic technology enabling miRNAs detection available at the University basic research laboratory (REMER).

Target partners' expertise sought

We are looking for:

1. Medical facilities with Departments of Urology, Oncology, (Onco) Radiotherapy, pathology and radiology.
    a. Type of cancer: testicular cancer (any stage and treatment)
    b. Type of sample: blood
    c. Clinical information: on stage treatment and on follow-up outcomes available for a minimum of 2 years after inclusion.
    d. Follow-up: to be performed according to the minimum requirements to the European Association of Oncology (ESMO) and European Association of Urology (EAU) for each stage.
    e. Approach: the blood samples will be used to determine the new biomarker at diagnostic and at every follow-up visit.
    f. Specific requirements: complete clinical (laboratory and imaging) data at study entry diagnostic and during follow-up.
    g. Number of patients: to be determined

2. Genomic facilities where RNA sequencing (RNA-Seq) techniques can be performed according to a fix centralized protocol.

3. Analytic and computational facilities: clinical data will be centralized.

Key words
Testicular cancer; miRNAs; Bio-markers validation; Personalized therapy; Prognostic and Predictive factors; RNA sequencing

Short description of the organization

Istanbul Medipol University has seven affiliated hospitals in Istanbul of which Medipol Mega Hospital acts as the umbrella center where Urological Oncological care is centralized. The department of Urology has a structured tumor board integrated by urologists, oncologists, radiotherapy, radiologists , molecular imaging specialist and pathologists. The tumor board meets once a week.
Istanbul Medipol University was founded in 2008 and has a basic research and regenerative medicine center (REMER) with high scientific output. The University has also departments of statistics and of Epidemiology.

The population sample corresponding to the project will be collected in the different European hospitals and the target new biomarker sequencing techniques will be either centralized and processed in a central laboratory or according to a standard technique and protocol for those centers with genetic laboratory available.

Analysis of clinical and laboratory data will be centralized in Medipol University.

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