Innovation Portfolio
17SLB002

Diagnostic test for azoospermia origin

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HIGHLIGHTS

- ✓ **Non-invasive azoospermia biomarkers & Kit development**
- ✓ **High sensitivity and specificity (>90%)**
- ✓ **Effective azoospermia test in seminal**

TECH STATUS

- ✓ **TRL: Validated in the lab**
- ✓ **IP: Patent application EP18382194**

Problem to be solved

Until now, there is no test with clinical utility to classify the origin of the sperm defects in semen and the spermatogenic reserve of the testis, determinant conditions for an assisted reproductive treatment in those men with no sperm in their ejaculate or azoospermia

Background

A significant proportion of male infertility is accompanied by the absence of sperm in the ejaculate, resulting from obstruction in the genital tract (obstructive azoospermia with conserved spermatogenesis) or from testicular spermatogenic failure (secretory azoospermia presenting no sperm or few spermatozoa in the testis). Testicular biopsy is performed in order to determine the histological diagnosis of azoospermia and for the extraction of spermatozoa to be used in assisted reproduction treatments. Additionally, referring to secretory azoospermia, the testicular biopsy does not always reflect the overall state of the testis due to heterogeneous spatial distribution of spermatogenesis in secretory alterations, and their practice should be frequently repeated. In this context, it is reasonable to search for diagnostic and prognostic markers in human fluids in order to avoid an abusive use of invasive methods.

Technology

The present invention is focused on the evaluation and assessment of the expression levels of miRNAs contained in exosomes from semen in severe spermatogenic disorders and obstructive azoospermic men. This group of miRNAs could be used as non-invasive biomarkers that contribute in the diagnosis of the origin of azoospermia. Additionally, several miRNAs could be used as non-invasive biomarkers to predict the presence of spermatozoa in secretory azoospermia in order to avoid unnecessary biopsies.

Applications

This group of miRNAs could be used as non-invasive biomarkers that contribute in the diagnosis of the origin of azoospermia. Those azoospermic cases predicted to be originated from an obstruction of the genitourinary tract have many chances to obtain sperm from the testicular biopsy for the assited reproduction treatment. Additionally, several miRNAs could be used as non-

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invasive biomarkers to predict the presence of spermatozoa in secretory azoospermia in order to avoid unnecessary biopsies.

Technology status

Semen samples were obtained from normozoospermic (Nz) fertile individuals (control group); individuals with obstructive azoospermia (OA) with conserved spermatogenesis including both, men successfully vasectomized (OA-V) and individuals presenting pathological naturally occurring- obstruction in the genital tract (OA-N); and infertile man diagnosed with secretory azoospermia (SA) (no sperm in semen sample due to spermatogenic failure).

We have determined one miRNA that is able to distinguish azoospermic samples derived from a spermatogenic disorder from those derived from an obstruction with high sensitivity and specificity (>90%). The efficacy of the predictive test was even better when the blood FSH values were included in the analysis. Additionally, the combination of expression data of two miRNAs is able to discriminate those secretory azoospermic samples without a reserve of sperm in the testis with a 100% of specificity and sensitivity.

Moreover, the kit technology is currently being developed in order to create an easy to use and cheap kit to determine the azoospermia origin.

Market Opportunity

Azoospermia represents up to 20% cases of male infertility.

Business Opportunity

Co-development or license agreement

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