Could miRNAs be used as markers for distinguishing undescended testicles from retractile testicles

No NCT number assigned yet

31.03.2022

INFORMED CONSENT FORM

This study you are participating in is a scientific study investigating miRNAs associated with undescended and retractile testes. Cryptorchidism, or undescended testes, is a common congenital anomaly in children. This term is sometimes used for retractile or undescended testes, but in this case, it refers to cases where the scrotum appears empty. Retractile testes are a different form of undescended testes, with the difference being that the testes may descend into the scrotum or, if descent is performed during the examination, may re-emerge. In these cases, treatment is determined based on the length of time the testes remain elevated. Instead of delays in diagnosis, undescended testes can lead to cancer development in the ovarian tissue and infertility later in life. Even current treatment guidelines address issues regarding retractile testes. The accuracy of monitoring the time the testicle spends in the scrotum, as requested by the patient, is debatable. In short, the time elapsed until surgical treatment in these cases impacts the future lives of these patients. And in many cases, it is impossible to distinguish between follow-up cases and undescended testes requiring urgent treatment. Early diagnosis of these cases, which may cause problems in the future, is critical for treatment planning. There is a significant need for markers that can assist us in this regard. The study plans to measure microRNA (miRNA) levels in serum samples from patients diagnosed with undescended and shy testes and from healthy controls. Based on the obtained data, the aim is to determine whether these miRNAs can be useful markers for distinguishing between undescended and shy testes. The results of this project are intended to be published in scientifically respected international journals, and if the desired results are obtained, new targets indicating the presence of undescended and shy testes will be added to the scientific database.

The results of this research are intended to be published in scientifically respected international journals, and if the desired results are obtained, it is intended to contribute to the literature on undescended testes. You will not receive any treatment in this study. Your participation in this study is expected to last two years, and the number of volunteers will be 30.

If you agree to participate in this study, you will be divided into three groups: the undescended testes group, the shy testes group, and the healthy volunteer group. There will be no change in the current treatments of patients with undescended testes and shy testes upon participation in this study. If you agree to participate in the study, a one-time blood sample will be collected using a 22G syringe. This blood sample is already routine and carries risks, such as bleeding, bruising, edema, and infection, although these procedures are unlikely. There will be no fees, shipping, or storage charges for this procedure. Blood samples from the patient and control groups will be collected in 13x100mm, 5mL biochemistry tubes. These samples will be centrifuged for 10 minutes at 3000rpm. The supernatant, free of particles, will be separated into 1.5ml Eppendorf tubes and stored in a deep freezer at -80°C until the time of the study. miRNA will be obtained through various procedures.

You will have no responsibilities related to this research (e.g., following the treatment schedule, following the investigator's recommendations, bringing medication boxes, etc.).
This research may involve local risks and discomfort such as bleeding, ecchymosis, edema, and infection; however, the expected benefits include timely diagnosis and effective treatment for pediatric patients whose treatment may be delayed because the distinction between undescended and swollen testes cannot be made. In the event of a research-related harm, treatment will be provided by the responsible researcher, and any resulting expenses will be covered by Mevlüt Keleş (this is not mandatory for research that does not require approval from the Ministry of Health). Any developments that may concern you during the research will be immediately notified to you or your legal representative. For additional information about the research or any problems, adverse effects, or other concerns related to the study, you can contact Dr. Mevlüt Keleş at 532 312 4079.

You will not be paid for your participation in this research (the amount of payment must be stated); furthermore, no fees will be charged to you or your social security institution for any examinations, tests, or medical care services within the scope of this research. This research is supported by the BAP (University Research Fund).
Participation in this research is entirely voluntary.

Volunteer's Name and Surname: Address: Phone and Fax: Date and Signature:	**The researcher who made the statements:** Name-Surname: Position: Address: Phone-Fax: Date and Signature:
For those under guardianship or wardship, the parent or guardian's: Name-Surname: Address: Phone-Fax: Date and Signature:	**The organization official/meeting witness who witnessed the consent process from beginning to end:** Name-Surname: Position: Address: Phone-Fax: Date and Signature: