Study Protocol and Informed Consent Form (ICF)

Title:
Assessment of Differences in Body Composition, Physical Fitness, and Thermoregulatory Response to Incremental Exercise in Young Boys With Type I Diabetes and Healthy Soccer Players (BCFTYR)

Unique Protocol ID:
654/24

Date of Creation:
10.10.2024

Study protocol

The scientific study will be conducted at the Human Movement Analysis Laboratory, Labthletics, at the Eugeniusz Piasecki University of Physical Education.

Participants may consume a light meal consisting of a sandwich and up to 0.5 liters of water. For diabetic participants, the meal will be determined by a diabetologist.

The procedure will include:

1. **Arrival and Acclimatization**: Participants will arrive at the laboratory and have time to acclimatize.
2. **Body Composition Analysis (DXA)**: Body weight and height will be measured using a digital stadiometer (SECA 285, SECA, Hamburg, Germany). Body composition will then be assessed using dual-energy X-ray absorptiometry (DXA) with the Lunar Prodigy Pro DXA device (GE Healthcare, Madison, WI, USA) and enCORE v. 16 SP1 software. All DXA scans will be performed and analyzed by the same trained technician according to the manufacturer's protocols.
3. **Capillary Blood Sampling and Thermographic Assessment**: Blood samples will be collected for analysis, followed by thermographic imaging of the lower limbs.
4. **Exercise Test Initiation**: Participants will perform a graded treadmill running test to exhaustion. During breaks between exercise stages, capillary blood samples will be collected, and thermographic images will be taken.
    - The graded exercise test will be conducted on a treadmill (H/P Cosmos Pulsar, Sports & Medical, Nussdorf-Traunstein, Germany). After 3 minutes of standing on the treadmill, participants will walk at 4 km/h for the first 3 minutes, then the speed will increase to 8 km/h. After this point, the treadmill speed will increase by 2 km/h every 3 minutes until voluntary exhaustion. Blood samples will be collected at the end of each 3-minute stage, starting from a speed of 10 km/h. Respiratory parameters will be measured using an ergospirometer (Cortex Metamax 3B R2, Leipzig, Germany) and analyzed with MetasoftStudio v. 5.1.0 software (Cortex-Metamax 3B R2; Cortex Biophysik, Leipzig, Germany). A Polar Bluetooth Smart HR H6 heart rate monitor (Polar Electro Oy, Kempele, Finland) will be used to monitor heart rate (HR). The Rating of Perceived Exertion (RPE) scale will be used to monitor fatigue levels during exercise.
5. **Post-Exercise and Rest**: After the exercise, capillary blood samples will be collected, and a thermographic assessment will be conducted. Participants will then have 30 minutes to rest, during which thermographic measurements and capillary blood sampling will continue.
6. **Study Conclusion**: After the study, participants may leave the laboratory.
7. **Glycemic Monitoring Systems**: Athletes with type 1 diabetes (study group) and healthy individuals (control group) will also have a continuous glucose monitoring sensor (FreeStyle Libre, Abbott Medical, Warsaw, Poland, or similar) placed on the back of one arm. The sensors will be applied one week before the exercise test and will remain active for 14 days. Continuous glucose monitoring will allow for the assessment of metabolic control before the study, the impact of increasing physical activity (aerobic-anaerobic exercise) on current glucose levels, and its long-term effects (assessment of post-exercise hypoglycemia risk).

All data collected during the study will be confidential and used solely for research purposes. Measures will be taken to ensure the privacy and confidentiality of participants' personal data. The results of the medical experiment, data, and biological material collected during the study may be used for future commercial purposes in accordance with applicable laws.

All questionnaires and surveys will be provided to participants at the beginning of each research session. The time required to complete them will depend on the individual needs of each participant but should not exceed 15 minutes. Sample questionnaires and surveys will be provided to participants before the study begins.

All procedures are voluntary, and participants may withdraw from the study at any time. The safety and well-being of participants are our top priorities.

Patient Information Form
Poznań, ……

The aim of the study is to evaluate differences in body composition, exercise capacity, and exercise-induced thermoregulation between young athletes (soccer players) with type 1 diabetes and their healthy peers (also soccer players).

The scientific study will be conducted at the Human Movement Analysis Laboratory, Labthletics, at the Eugeniusz Piasecki University of Physical Education from November 15, 2024, to June 1, 2025. The research procedure will be as follows:

1. **Pre-Study Meal**: Participants may consume a light meal consisting of a sandwich and up to 0.5 liters of water. For diabetic participants, the meal will be determined by a diabetologist.
2. **Arrival and Acclimatization**: Participants will arrive at the laboratory and have time to acclimatize. All questionnaires and surveys will be provided at the beginning of each research session, with a completion time of 15 minutes.
3. **Body Composition Analysis (DXA)**
4. **Capillary Blood Sampling and Thermographic Assessment**
5. **Exercise Test and Post-Exercise Rest (30 minutes)**

Medical Benefits:

- Participants may learn to use modern methods for monitoring and managing blood glucose levels more effectively, which can lead to better control of type 1 diabetes.
- Reduced risk of complications such as retinopathy, neuropathy, or nephropathy.
- The estimated duration of the research procedure is approximately 1 hour.

Reasons for Terminating the Medical Experiment: If participants experience serious health issues such as hypoglycemia, hyperglycemia, or other complications related to type 1 diabetes, or if new comorbidities arise.

All data collected during the study will be confidential and used solely for research purposes. Measures will be taken to ensure the privacy and confidentiality of participants' personal data. The results of the study, data, and biological material may be used for future commercial purposes in accordance with applicable laws.

The University of Physical Education holds a general liability insurance policy (No. 1022670362 issued by PZU S.A.) covering liability for damages resulting from conducting medical research.

Planned Use of Research Results: Scientific publications, conference presentations, recommendations for better glucose monitoring, development of individualized dietary plans tailored to exercise intensity, creation of new technologies for glucose monitoring, and education of coaches and caregivers about the specific needs of young athletes with type 1 diabetes.

The scientific study will be funded by the research funds of the University of Physical Education in Poznań.

All procedures are voluntary, and participants may withdraw from the study at any time without providing a reason and without any negative legal consequences. The safety and well-being of participants are our top priorities.

The data controller is the University of Physical Education, located at ul. Królowej Jadwigi 27/39, 61-871 Poznań. Participants have the right to access their data, correct it, delete it, restrict its processing, transfer it, object to its processing, and withdraw consent at any time. Withdrawal of consent does not affect the lawfulness of processing based on consent before its withdrawal.

Participant's Signature: _____