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SPECTROPHON Glucometry Monitor Accuracy Study

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Study Design

This study will examine the accuracy of Spectrophon NIGM incorporated in smart watches that noninvasively and indirectly detect the level of glucose in human blood. Adult subjects (n=200; both healthy individuals and participants with diabetes) will be recruited for the study in Maale Carmel Mental Health Center (MCMHC). In parallel to glucose measurements with NIGM, blood will be collected and the glucose level will be checked. An intravenous cannula (Venflon) will be inserted in cubital vein and blood will be collected twice in the beginning and at the end of the procedure and checked for glucose level with YSI 2300 Glucose Analyzer.

The measurements will be performed twice: before meal (subject should be in fasting state) and after meal with one-hour interval between two measurements.

The results of the measurements of the spectrometer biosensor will be compared to the results obtained from the YSI 2300 Laboratory Glucose Analyzer.

Inclusion criteria *(for the group of healthy participants*):

Healthy individuals between ages 18 and 75 that do not have diabetes and are able to sign informed consent form.

Exclusion criteria *(for the group of healthy participants*):

Hepatitis or HIV, tuberculosis, diabetes, hemophilia and other serious coagulation disorders, significant impaired venous access, pregnancy.

Inclusion criteria *(for the group of participants with diabetes):*

Clinical diagnosis of diabetes (I type, II type), age: 18-75, able to sign

informed consent form.

Exclusion criteria *(for the group of participants with diabetes)*:

hepatitis or HIV, tuberculosis, hemophilia and other severe coagulation disorders, significantly impaired venous access, pregnancy.

Procedure

In the beginning of the experiment a participant must be in fasting state.

A blood sample is collected and checked for the glucose level with the reference devices YSI 2300 Glucose Analyzer.

NIGM is applied to the participant's skin after taking blood sample.

NIGM non-invasively measures glucose level in triplicate samplings.

After blood sampling, the participant receives food (no limitations to food type and quantity).

60 min. after meal, the second blood sample is collected and checked for the glucose level. NIGM is applied again to participant’s skin after taking blood sample. NIGM non-invasively measures glucose level in triplicate samplings.

The application automatically saves every measurement into archive. To better control the process, the manual fixation of data obtained by NIGM is performed.

Statistical analysis

Mean absolute relative difference between Spectrophon NIGM, YSI 2300 Laboratory Glucose Analyzer and Accu-Chek Performa NC will be estimated for every sample to control the accuracy of the obtained data.

Regression analysis tools will be used to estimate the accuracy of NIGM measurements.

Principal investigator

Prof. Anatoly Kreinin

Signature