CELLMEDX (CANADA) CORP.

CLINICAL STUDY REPORT

An Observational Clinical Trial to Examine the Improvement of E Balance Pro Therapy on Diabetes and Related Complications

PROTOCOL #: CELLRPD-160001

Development Phase:	Phase IIA
First Subject Enrollment:	28 February 2017
Last Subject Completion:	20 July 2017
Report Date:	08 January 2018

Sponsor Name: CellMedX (Canada) Corp.

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This trial was conducted in accordance with the ethical principles of Good Clinical Practice, per the ICH Harmonized Tripartite Guideline.

SIGNATURE PAGE

STUDY TITLE: An Observational Clinical Trial to Examine the Improvement of E Balance Pro Therapy on Diabetes and Related Complications

STUDY AUTHORS:

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15 Jan. 2018
Date

Jennifer Ellis
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15 JAN 2018
Date

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study:

Richard Tytus, M.D., Principal Investigator

15/JAN 2018
Date

SYNOPSIS

Name of Sponsor/Company: CellMedX (Canada) Corp.		
Name of Finished Product: E Balance Pro		
Name of Active Ingredient: Micro-current therapy		
Title of Study: An Observational Clinical Trial to Examine the Improvement of E Balance Pro Therapy on Diabetes and Related Complications		
Study Centre: Hamilton Medical Research Group 700 Main Street East Hamilton, Ontario L8M 1K7		
Publications (reference): Not applicable		
Studied period (years): Date first subject enrolled: 28 February 2017 Date last subject completed: 20 July 2017		**Phase of development:** Phase IIA
Objectives: The objective of this clinical trial was to determine the impact of E Balance Pro Therapy micro-current treatment, as a supplement to standard treatment, on the course of disease and complications associated with diabetes.		
Methodology: This was an open label, observational, evaluation study in adults with a diagnosis of type 1 or type 2 diabetes, who satisfied the inclusion/exclusion requirements. Observations during the study and after three (3) months of treatment were compared to the subject's baseline and medical history. After three (3) months, study data was analyzed to determine if a longer observation period, or additional subjects, was required to attain sufficient data endpoints.		
Number of subjects (planned and analyzed): Planned: 30 adults with a diagnosis of type 1 or type 2 diabetes. Analyzed: 30		
Inclusion Criteria I1. Male or female adults $\geq$ 18 years of age. I2. HbA1c 7.0% to 11.0% (inclusive). I3. Body mass index 40.0 kg/m^2 or less.		

I4. Non-smoker, or ex-smoker ≥3 months.
I5. Female participants of childbearing potential [i.e. not surgically sterilized or post-menopausal (greater than one year since last menses)] must have negative urine pregnancy test, at Screening, and must be using an effective birth control method, defined as:
- Continuous use of oral, or long acting injected, contraceptive for at least 2 months prior to study entry, or
- Use of an intra-uterine device or implantable contraceptive, or
- Use of double barrier methods of birth control, or
- Abstinence from heterosexual intercourse.

I6. Currently on lifestyle management and/or standard treatment for diabetes.
I7. Currently under the care of a physician.
I8. Able and willing to perform self-monitoring of plasma glucose regularly.
I9. Willing to avoid alcohol consumption for 24 hours prior to every clinic visit.
I10. Willing to maintain a stable body weight, activity level and dietary pattern except for use of the study products, as directed.
I11. Willing and able to provide informed written consent prior to any study procedures.

Exclusion Criteria

E1. Pregnancy or lactation, or participant unwilling to take appropriate contraceptives for the duration of the study
E2. History of significant cardiovascular or coronary heart disease (CVD or CHD) as defined by having had a coronary artery bypass procedure, coronary stent or angioplasty, or myocardial infarction in the past six (6) months.
E3. Current or recent (within six months of Visit 1) history of significant gastrointestinal, renal, pulmonary, hepatic or biliary disease, other endocrine diseases, or invasive weight loss treatment.
E4. Subjects currently using pacemakers.
E5. History of epilepsy.
E6. Uncontrolled hypertension (SBP ≥ 180 and/or DBP ≥ 105 mm Hg) and unstable use (i.e. initiation or change in dose) of antihypertensive medications, or thyroid hormone replacement medications, within 3 months of Visit 1.
E7. Screening plasma creatinine above 130 µmol/L or ALT more than twice (2x) upper limit of normal.
E8. Use of **anticoagulants** such as (not exhaustive) warfarin (Coumadin), dabigatran (Pradaxa), apixaban (Eliquis) or rivaroxaban (Xarelto). **NOTE: Anti-platelet agents** such as Plavix are allowed.
E9. Use of prescription non-steroidal anti-inflammatory drugs ([NSAIDs] or daily use of over-the-counter (OTC) NSAIDs >1month), steroids, corticosteroids, or any other prescription anti-inflammatory drugs within three (3) months prior to Visit 1.

E10. Use of any weight-loss programs or medications (prescription or OTC) such as lipase inhibitors, within three (3) months of Visit 1.
E11. History of cancer (excluding non-melanoma skin cancer and basal cell carcinoma) in the past five (5) years.
E12. Alcohol or drug abuse (alcohol use of > 2 standard alcoholic drinks per day; one drink = 12oz. beer, 4 oz. wine, 1.5 oz. hard liquor), within 6 months of screening visit.
E13. Planning to undergo surgery during the study period or up to one (1) month after the study.
E14. Known allergy or intolerance to the test products or placebo.
E15. Unwilling or unable to abide by the requirements of the protocol.
E16. Any condition that would interfere with the participant's ability to comply with study instructions, might confound the interpretation of the study, or put the participant at risk.
E17. Use of an investigational health product, or has participated in a research study, within 30 days prior to first study visit

Test product and mode of administration: 15-minute treatment, twice a week on "Wellness Program".

Mode of administration: local

Rescue medication: None

Duration of treatment: Twelve weeks (approximately three months) with possible extension.

Criteria for evaluation:

Efficacy: Assessments of changes from Baseline for the following: HbA1c, biochemistry assessment of disease, including insulin sensitivity and renal function, patient-reported changes in complications arising from diabetes, including high blood pressure, neuropathy, wound healing, and foot pain.

Safety: Adverse Events (AEs), routine haematology and chemistry, biometrics and vital signs.

Statistical methods:

Trial Results: Descriptive statistics were used to provide an overall summary of the observations. A linear ANOVA model was used to compare the treatment and control group for biometrics (BMI, height, weight), and the primary efficacy endpoint, HbA1c.

SUMMARY – CONCLUSIONS

EFFICACY RESULTS:

Primary Efficacy Endpoint: On average, the mean HbA1c decreased by 0.16% ±0.82 following the treatment intervention at the end of study (EOS) compared to baseline HbA1c. Notably, there were no significant differences in screening, EOS, or change from baseline in HbA1c between the treatment and control group.

Secondary Efficacy Endpoints:

Insulin Sensitivity: On average, the post-treatment glucometer reading decreased relative to the pre-treatment reading for most visits. However, when comparing the difference in post-treatment glucometer readings at visits to baseline, on average the glucometer readings increased.

Insulin Resistance: On average, there was a trend towards a decrease in markers assessing insulin resistance, including fasting blood glucose, plasma insulin and HbA1c compared to baseline.

Blood Pressure: On average, there was a trend towards a decrease in blood pressure, as measured by systolic and diastolic blood pressure compared to baseline. Interestingly, the mean change from baseline in both systolic and diastolic blood pressure decreased gradually from weeks 1-7, plateauing from week 7 to the end of the study at week 11.

Kidney Function: On average, there was a trend towards a decrease in one marker assessing kidney function, which was eGFR compared to baseline. Other kidney function markers, including BUN and creatinine slightly increased from baseline; however, these markers were largely within normal range, and any out of range results were not considered clinically significant.

Diabetic Complications: Although no changes were reported in subjects with pre-existing diabetic complications, two (2) subjects without diagnosed complications reported feeling less pain or coldness in their extremities in diary entry comments reported at visit 2b or 3b. Notably, three (3) subjects reported increased sweet cravings, or eating more sweet foods/beverages to help raise blood glucose in diary entry comments after visit 2b, 3b or 9b.

SAFETY RESULTS:

There were no significant treatment related adverse events or abnormalities in routine haematology, biochemistry, vital signs, or physical findings for the duration of this study. The treatment was considered safe for the purposes of this study.

CONCLUSION:

In conclusion, there were several encouraging trends in HbA1c, and secondary efficacy endpoints assessing insulin resistance, insulin sensitivity, blood pressure and kidney function following E Balance Pro treatment which warrant further exploration. Most importantly, future studies evaluating the role of E Balance Pro therapy as an adjuvant therapy in diabetes can use this HbA1c data to design a double-blind, placebo controlled trial that is adequately powered to detect a difference in HbA1c between placebo and treatment groups if such a treatment effect exists.

Date of the report: 08 January 2018