ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: February 9, 2024

ClinicalTrials.gov ID: NCT06256172

Study Identification

Unique Protocol ID:	M101
Brief Title:	Medlink for Diagnosing of Diabetes Mellitus, COPD, CHF, Myasthenia Gravis and Hypertension
Official Title:	Medlink for Diagnosing of Diabetes Mellitus, COPD, CHF, Myasthenia Gravis and Hypertension
Secondary IDs:	

Study Status

Record Verification:	February 2024
Overall Status:	Completed
Study Start:	June 16, 2023 [Actual]
Primary Completion:	December 16, 2023 [Actual]
Study Completion:	December 16, 2023 [Actual]

Sponsor/Collaborators

Sponsor:	Olawuyi Racett Nigeria Ltd
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 101 Board Name: OLAWUYI RACETT NIGERIA LTD Board Affiliation: OLAWUYI RACETT NIGEIRA LTD. Phone: 2027262505 Email: TEGAE@GWMAIL.GWU.EDU Address: OLAWUYI RACETT NIGERIA LTD. KEMPHOUSE, 160 CITY ROAD EC1V 2NX,

LONDON, UNITED KINGDOM RC14668218

Data Monitoring: Yes

FDA Regulated Intervention: No

Study Description

Brief Summary: MEDLINK IS A POCKET-SIZED MEDLINK is a pocket-sized, verbally interactive, programmable medical device that allows physicians to select which medical measurements they would like to take for a specific patient. The Physiological Parameters that can be measured by MEDLINK include, but is not limited to: Electrocardiography (ECG), Blood Pressure, Heart Rate, Blood Glucose, Pulse Rate, Blood Oxygen Saturation (SPO2), Electromyography (EMG) body temperature, and Respiratory Data. MEDLINK is a pocket-sized, verbally interactive, programmable medical device that allows physicians to select which medical measurements they would like to take for a specific patient.

When the patient takes MEDLINK home and switches it on, the device verbally guides the patient to acquire the measurements requested by the his or her physician.

This information is transmitted to the physican's email for medical analysis, check up and/or follow up.

This Study was executed by TWO (2) MEDICAL CONSULTANTS: Dr. Michael Olawuyi (mgolawuyi@gmail.com) and Dr, Matthew Olawuyi (olawuyiracettnigerialtd@outlook.com)

Detailed Description: MEDLINK is a pocket-sized, verbally interactive, programmable medical device that allows physicians to select which medical measurements they would like to take for a specific patient. The Physiological Parameters that can be measured by MEDLINK include, but is not limited to: Electrocardiography (ECG), Blood Pressure, Heart Rate, Blood Glucose, Pulse Rate, Blood Oxygen Saturation (SPO2), Electromyography (EMG) body temperature, and Respiratory Data. After programming of the device by the Physician, MEDLINK can be given to the desired patient to take home for Remote Patient Monitoring (RPM).

When the patient switches on the device at home, MEDLINK verbally guides the patient to acquire the measurements requested by his or her Physician. This information is automatically and wirelessly transmitted to the Physician’s Mobile Phone and Email Address for medical analysis, check up, and/or follow up. MEDLINK has its own software application that allows the Physician to view and analyse the measured Physiological Parameters for any Patient. MEDLINK also has the potential to allow Patient-Physician Communication during the RPM Period.

One of the key innovations of MEDLINK is that it is able to acquire a diverse range of physiological parameters. This makes it useful to physicians in different areas of specialization in the medical field. In addition to this, MEDLINK also accurately measures all Physiological Parameters of the Patient through a single digit finger being inserted into the appropriate position in the pocket-device, making it extremely easy to use. MEDLINK is the first medical device that performs blood glucose measurement using Infrared Technology, as opposed to the standardized lancet finger-pricking technology.

MEDLINK allows Physicians in any specialization to monitor patients outside of the hospital setting for as long as is needed. It can be used to monitor patients after they have been discharged from the hospital. It also allows individuals to have quality access to basic health care.

Ten Patients were recruited for this Study and tested the use of MEDLINK in measuring physiological parameters and providing remote access to basic health care.

This Study was executed by TWO (2) MEDICAL CONSULTANTS: Dr. Michael Olawuyi (mgolawuyi@gmail.com) and Dr, Matthew Olawuyi (olawuyiracettnigerialtd@outlook.com)

Conditions

Conditions: Diabetes Mellitus
Chronic Obstructive Pulmonary Disease
Congestive Heart Failure
Myasthenia Gravis
Hypertension

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Prevention

Study Phase: N/A

Interventional Study Model: Single Group Assignment

Number of Arms: 1

Masking: None (Open Label)

Allocation: N/A

Enrollment: 10 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Medlink RPM The 10 Patients enrolled in this arm tested the ue of Medlink in Measuring and reporting their Physiological Paramters in Oder to remotely obtain access to health care for the following diseases: Myasthenia Gravis, Hypertension, Chronic Heart Failure, Diabetes Mellitus, and Chronic Obstruction Pulmonary Disorder.	Device: Medlink The 10 Patients enrolled in this arm tested the ue of Medlink in Measuring and reporting their Physiological Paramters in Oder to remotely obtain access to health care for the following diseases: Myasthenia Gravis, Hypertension, Chronic Heart Failure, Diabetes Mellitus, and Chronic Obstruction Pulmonary Disorder.

Outcome Measures

Primary Outcome Measure:

1. Electrocardiography (ECG) (1 PQRS Interval acquired) using the ECG unit in Medlink
   1 PQRS Interval is acquired.

   [Time Frame: Measurement is done Once daily for 2 weeks]

2. 5 readings of Blood Pressure (Systolic and Diastolic Pressure) in mmHg using the Blood Pressure unit in Medlink is acquired and the average value is reported
   Acquisition of 5 readings of Blood Pressure (Systolic and Diastolic Pressure) in mmHg and the average value is reported

   [Time Frame: Measurement is done Once daily for 2 weeks]

3. 5 readings of 1 beat of Heart Rate in bpm is acquired using the Heart Rate unit in Medlink and the average value is reported.
Acquisition of 5 readings of Heart Rate in bpm and the average vallue is reported

[Time Frame: Measurement is done Once daily for 2 weeks]

4. 5 readings of Blood Glucose in mmol/L using the Infrared Glucometer unit in Medlink is acquired and the average value is reported
Acquisition of 5 readings of Blood Glucose in mmol/L and the average value is reported

[Time Frame: Measurement is done Once daily for 2 weeks]

5. 5 readings of Pulse in bpm using the Pulse Rate unit in Medlink and the average value is reported
Acquisition of 5 readings of Pulse in bpm and the average value is reported

[Time Frame: Measurement is done Once daily for 2 weeks]

6. 5 readings of SPO2 in percent using the SPO2 unit in Medlink and the average value is reported
Acquisition of 5 readings of SPO2 or Blood Oxygen Saturation and the average value is reported

[Time Frame: Measurement is done Once daily for 2 weeks]

7. 5 readings of Electromyography (EMG) Power in Analog Values in the Beta Band is measured using the EMG unit in Medlink and the average value is reported
Acquisition of 5 readings of Electromyography or Muscle Strength Power in the Beta band and the average value is reported

[Time Frame: Measurement is done Once daily for 2 weeks]

8. 5 readings of Body Temperature in Degrees Celcius using the Body Temperature Unit of Medlink and the average value is reported.
Acquisition of 5 readings of Body Temperature in Degrees Celcius and the average value is reported

[Time Frame: Measurement is done Once daily for 2 weeks]

9. 5 readings of Respiratory Data (FEV1, FVC, FEV1/FVC ratio) in L using the Respiratory unit in Medlink is acquired and the average value is reported.
Acquisition of 5 readings of Respiratory Data (FEV1, FVC, FEV1/FVC ratio) in L and the average value is reported

[Time Frame: Measurement is done Once daily for 2 weeks]

Eligibility

Minimum Age:	
Maximum Age:	
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	Yes
Criteria:	Inclusion Criteria:

- NONE

Exclusion Criteria:

- NONE

Contacts/Locations

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IPDSharing

Plan to Share IPD: Yes
Data Gathered from the Trial will be made available through Certified Publications

Supporting Information:
Clinical Study Report (CSR)

Time Frame:
Data is available as of 20/01/2024 until 20/01/2034

Access Criteria:
Data is available to all the public

URL:

References

Citations:

Links:

Available IPD/Information:

Documents

Study Protocol
Document Date: February 7, 2024
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