Sep 09, 2020

vBio Voice Analysis

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[1]vBio

In Development This protocol is published without a DOI.

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PROTOCOL CITATION

David Levesque 2020. vBio Voice Analysis. **protocols.io**
https://protocols.io/view/vbio-voice-analysis-bk6dkza6

CREATED

Sep 09, 2020

LAST MODIFIED

Sep 09, 2020

PROTOCOL INTEGER ID

41893

Demographic & Endpoints

1 **Study Protocol**
Ages Eligible for Study: 18 Years and older (Adult, Older Adult)
Sexes Eligible for Study: Male Female
All Accepts Healthy Volunteers: Yes
No Sampling Method: Non-Probability Sample
Sites: 60 hospitals, Africa, EU, Asia, U.S.

Study Populations
Patients with positive COVID-19 PCR test results within 14 days.
Healthy volunteers

Outcome measures
Accuracy of positive and negative test results generated by the vocal analysis software compared to PCR.

Primary endpoints (collected within 14 days of positive PCR results)
Two 30 second voice recordings
COVID-19 test results

Secondary Endpoints (optional)
IGG, IGM, other factors found via the voice analysis software
IGG, IGM levels post recovery (this is optional as it requires a second engagement with the patient, which we may do if we have appropriate funding)
Medications
Comorbidities/conditions
Age
Gender
Zip Code or other location information
Patient experience score on a scale of 1-5 (See potential instruments here:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4511995/

Inclusion & Exclusion Criteria

2 Inclusion Criteria:

1. Male or female, aged > 18 years
2. Provide a valid electronic informed consent form
3. Stated willingness to provide evidence of their lab test results
4. Pregnant or lactating women may participate

Exclusion Criteria:

1. Presence of tracheostomy or past tracheostomy with permanent change to the voice due complications that involved the vocal cords.
2. Prior surgery which may influence the vocal cords, e.g., laryngeal, tracheal or esophageal surgery
3. Prior head, neck or throat cancer treated with radical neck dissection and/or radiation therapy that may influence the vocal cords
4. Treatment with another investigational drug or device within 30 days prior to signing Consent

3 Proposed Study process

1. Partners for patients receives ethic board approval at the hospital
2. The hospital approves Partners for patients to contact their doctors about the study
3. Partners for patients speaks with doctors to educate them on the study protocol
4. Doctor or Research coordinator talks with patients about their interest in participating
5. a) Doctors could give us consent to talk to the patient
6. Doctors/ research coordinator emails the consent to patients
7. a) Patient signs the PDF consent form and emails it back to the doctor
8. b) Doctor emails the patient the link to the GoNoGo study interface
9. 1. We could add the consent form to the study interface
10. The patient records their voice sample
11. The patient enters their name and email address
12. The audio file and name and email address is sent to GoNoGo
13. The file is analyzed
14. The patient's test results are retrieved from the Clinerion database and added to the GoNoGo data to confirm diagnosis
15. Patients are invited to participate in an online support community
16. Upon study completion, lay person study summaries are delivered to patients via email or an app