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Study to evaluate the operational suitability of two point-of-care assay devices in a clinical setting

Submission date
12/09/2022

Recruitment status
No longer recruiting

Registration date
15/09/2022

Overall study status
Completed

Last Edited
15/09/2022

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
COVID-19 is caused by a novel beta-coronavirus known as Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). Interleukin-6 (IL-6) is a protein that is produced in response to injury or severe infections such as COVID-19. In response, the patient's immune system tries to defend the body by producing antibodies. An antibody is a protein used by the immune system to identify and neutralize foreign objects such as bacteria and viruses.
The aim of this study is to evaluate and establish the feasibility of using two medical devices as point of contact (POC) test platforms in a clinical trial setting. A point of care test is a test that can be performed in a doctor's office or emergency room instead of a laboratory. The two platforms being assessed are an IL-6 test developed by Proxim and a COVID-19 test developed Qorvo. The Proxim IL-6 test helps to quantify the level of IL-6 in blood samples rapidly and Qorvo COVID-19 test is used for fast detection of SARS-CoV-2. At the start of this study, neither the Qorvo COVID-19 test, and Proxim IL-6 test are approved by health authorities for the diagnosis of COVID-19 and conditions related to elevated IL-6 levels in blood.

Who can participate?
People who are over 21 years of age and have a confirmed diagnosis of COVID-19, have COVID-19 symptoms and/or have a condition associated with elevated IL-6

What does the study involve?
Participants will be a part of this study for one day. The study includes:
Screening period: All participants will be screened to make sure they are a good fit before the study begins.
Sample collection: A blood sample and nasal swab sample will be collected from all participants to test for IL-6 using the Proxim IL-6 test and for COVID-19 using the Qorvo COVID-19 test. A blood sample will be drawn from a vein (venipuncture).
Follow up: To check on the participants after sample collection.
Users (nurses or lab technicians who load the sample in the cartridge and run the samples on

both POC devices) will provide feedback on device training effectiveness, ease of use, and user satisfaction through completion of the Device Training questionnaire, Ease of Use questionnaire, and the Satisfaction Questionnaire, respectively.

What are the possible benefits and risks of participating?
Participants will not receive any benefit from participating in this study. Participants will receive IRB-approved monetary compensation for one single visit. Participants may experience some side effects during blood draw and nasal swab sample collection. The most common risks from blood sample collection through venipuncture include discomfort, pain, collection/pooling of blood outside blood vessels (hematoma), bruising/discoloration of the skin due to rupture of blood vessels under it (ecchymosis), and rarely feeling faint (vasovagal reaction).Nasal swab sample collection has essentially no risks, other than slight discomfort. On very few occasions, people experience nosebleeds (epistaxis) and broken swab tips.

Where is the study run from?
F. Hoffmann-La Roche Ltd (USA)

When is the study starting and how long is it expected to run for?
June 2021 to December 2022

Who is funding the study?
F. Hoffmann-La Roche Ltd (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
XE43505

Study information

Scientific Title

Evaluation of logistical feasibility in implementation of two point-of-care assay technologies in a clinical trial setting

Study objectives
The purpose of this study, and intended use of these devices, is to establish feasibility of two point-of-care (POC) assay technology platforms as bioanalytical tools for soluble biomarkers, pharmacokinetics (PK), and anti-drug antibodies (ADA) for routine use in a clinical trial setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/08/2022, Advarra, Inc. (6100 Merriweather Dr. Suite 600, Columbia, MD 21044, USA; +1 (0)410 884 2900; cirbi@advarra.com), ref: Pro00063146

Study design
Single-arm unblinded clinical trial logistics study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection) or COVID-19 symptoms, or a disease or condition associated with elevated interleukin-6 (IL-6) concentrations

Interventions
Participants will be required to provide a blood sample, drawn via venipuncture, for the Proxim IL-6 assay, and a nasal swab, for the Qorvo COVID-19 antigen assay, during their single visit to the site (Day 1). Thereafter, users, who are lab technicians or trained nurses, will run the samples on the POC instruments. This will allow the users to compare the two instruments and provide feedback on device training effectiveness, ease of use, and user satisfaction for each POC platform through completion of the Device Training questionnaires, the Ease of Use questionnaires, and the Satisfaction questionnaire, respectively.

Intervention Type
Other

Primary outcome(s)
1. Device training effectiveness for each POC platform, assessed using the device training questionnaire, completed by each user (assessed after training and after processing all three samples from the user’s first participant)
2. Ease of use for each POC platform, assessed using ease of use questionnaire, completed by each user (assessed after training and after processing all three samples from user's fourth participant)
3. User satisfaction for both POC platforms, assessed using satisfaction questionnaire, completed by each user (assessed after processing all three samples from user’s last participant)
4. Elapsed time from starting sample collection to result on the POC instrument assessed using data collected from each sample (blood, plasma, and nasal) for each subject (approximately 6

months for all participants)
5. Number of data queries issued on test results as assessed by the sponsor over 6 months
6. Number of device failures or malfunctions assessed using data collected per sample over 6 months

Key secondary outcome(s))
Comparison of IL-6 results from whole blood and from plasma assessed using data collected from Proxim device for each participant over 6 months

Completion date
30/12/2022

Eligibility

Key inclusion criteria
Participants:
1. Diagnosed with COVID-19 or with COVID-19 symptoms; or a disease or condition associated with elevated IL-6 concentrations, such as localized (e.g., prosthetic joint infections, periodontitis) or systemic (e.g., sepsis) infections, autoimmune conditions (e.g., rheumatoid arthritis [RA], systemic lupus erythematosus [SLE], ankylosing spondylitis, inflammatory bowel disease [IBD]), or other inflammatory conditions
2. Aged ≥21 years at the time of signing Informed Consent Form

Users:
Users must be either a nurse or a technician

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Poor vascular access for venipuncture
2. Currently on anti-IL-6 therapy (e.g., Actemra)
3. Currently participating in another clinical trial of an unapproved investigational medical product (i.e., device, drug, biologic) that has not concluded the follow-up period

Date of first enrolment
19/09/2022

Date of final enrolment
30/12/2022

Locations

Countries of recruitment
United States of America

Study participating centre
Carbon Health
California
United States of America
91403

Study participating centre
DelRicht Research
Louisiana
United States of America
70124

Sponsor information

Organisation
F. Hoffmann-La Roche Ltd

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location

Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement.

IPD sharing plan summary
Not expected to be made available