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Hormones after COVID-19

Submission date
20/01/2021

Recruitment status
No longer recruiting

Registration date
31/01/2021

Overall study status
Completed

Last Edited
31/10/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The ongoing COVID-19 pandemic remains a significant public health concern. However, it is now recognised that following COVID-19, patients may experience symptoms such as fatigue. There is little data on how many people experience these symptoms and their duration. Commonly, tiredness may be related to hormone (endocrine) dysfunction in patients without COVID-19. However, the frequency of endocrine dysfunction after COVID-19 is unknown. Not only are coronaviruses associated with adrenal gland dysfunction, but other endocrine glands may also be affected. Patients with COVID-19 have been described as displaying abnormalities in thyroid hormones and male reproductive hormones.
In summary, the full hormone effects of COVID-19 are currently unknown. This study attempts to fully interrogate the endocrine system, so that participants can receive necessary treatment, and to provide further information to guide the clinician when caring for patients diagnosed with COVID-19.

Who can participate?
Men and women aged 18 and over who have been tested for COVID-19 at least 3 months ago. Individuals interested in taking part will be contacted by telephone and asked a series of questions to confirm their eligibility before attending for their research study visit.

What does the study involve?
The study consists of an initial 2-hour visit that takes place at least 3 months after initial symptoms, with up to three further study visits over the course of the year at 3-monthly intervals. During this appointment, participants will be asked several questions regarding their medical history, undergo a physical examination, followed by some blood tests, including a particular dynamic hormone test, called a Short Synacthen test, that assesses the function of the adrenal glands.

What are the possible benefits and risks of participating?
Taking part in the study will provide information regarding the participant's hormone system including the critical hypothalamic-pituitary-adrenal axis. Participation may identify hormonal problems that would have otherwise been undetected. This study may also help guide endocrine surveillance of these patients on a global scale to reduce illness and death.
Venepuncture for blood tests is a routine, well-tolerated and safe procedure, and will only be carried out by experienced physicians and nursing staff. The short synacthen test is an

established dynamic function test commonly used in routine endocrine care, with millions globally as part of routine endocrine investigations, and is well tolerated by patients. Synacthen is a synthetic form of a naturally occurring hormone and is not known to have any specific side-effects. However, to minimise any risk to participants, only experienced clinical personnel will undertake these tasks. Furthermore, participants will be monitored throughout the whole study visit by senior clinical staff.

Where is the study run from?
Charing Cross Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2020 to October 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Waljit Dhillo
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
288153

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 288153

Study information

Scientific Title
Endocrinopathies post COVID-19

Study objectives
It is known that some coronaviruses can affect the endocrine system, such as the adrenal glands, some weeks to months after initial infection. However, it is yet unknown whether COVID-19 affects the endocrine system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/09/2020, London Bridge Research Ethics Committee (Ground Floor, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8019; londonbridge.rec@hra.nhs.uk), REC ref: 20/HRA/4110

Study design
Physiological observational prospective study

Primary study design
Observational

Secondary study design
Prospective observational study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Patients who have had a test for COVID-19 will be invited to take part in the study. During their clinical research visit, a medical history will be taken, a physical examination performed and blood tests to assess the endocrine system will be completed. A short synacthen test will also be carried out to assess adrenal function.

Intervention Type
Other

Primary outcome measure
The proportion of patients with confirmed COVID-19 who show evidence of adrenal insufficiency on a short Synacthen test ≥3 months following their presentation with suspected COVID-19

Secondary outcome measures
Secondary outcome measures will include the following:
1. Proportion of patients previously diagnosed with COVID-19 with evidence of adrenal insufficiency on their first short Synacthen test who show adrenal recovery at subsequent visits at months 3, 6 and 9 months after initial study visit, whereby the first study visit takes place at least 3 months after initial presentation
2. Proportion of patients previously diagnosed with COVID-19 with evidence of other hormone disturbances (including thyroid and reproductive hormones) measured using serum thyroid function tests and serum reproductive hormone tests (LH, FSH, testosterone and oestradiol) at least 3 months after initial presentation

Overall study start date
16/09/2020

Completion date
16/10/2022

Eligibility

Key inclusion criteria
Patients aged ≥18 years with a clinical suspicion of COVID-19 infection will be invited to take part in the study. Those with a diagnosis of COVID-19, either on the basis of a positive result from real-time RT-PCR testing of a nasopharyngeal swab, or based on diagnostic clinical and radiological findings will be included in the COVID-19 group.

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
70

Key exclusion criteria
1. History of any medical, psychological or other condition, or use of any medications, including over-the-counter products, which, in the opinion of the investigators, would either interfere with the study or potentially cause harm to the participant.
2. History of blood donation within the past 3 months, or the intention to do so within 3 months of completing the study
3. Being pregnant or breastfeeding

Date of first enrolment
13/10/2020

Date of final enrolment
17/11/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College London
Charing Cross Hospital Campus
Fulham Palace Road
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Sponsor information

Organisation
Imperial College London

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Sponsor type
University/education

Website
http://www.imperial.ac.uk

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
1. Additional study documents including study protocol are available on request
2. The results of the study will be disseminated to participants. Furthermore, results will be disseminated to the scientific community by means of publication in peer-reviewed literature and presentation at national and international meetings.

Intention to publish date
16/09/2023

Individual participant data (IPD) sharing plan

All participants have been requested to provide consent for data sharing. Where this consent has been provided, anonymised datasets generated during the current study will be available upon request from Prof. Waljit Dhillo (w.dhillo@imperial.ac.uk) upon completion and publication of the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/07/2021	31/10/2022	Yes	No
HRA research summary			28/06/2023	No	No