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Can the Ava fertility tracker device detect early signs of COVID-19?

Submission date
10/04/2020

Recruitment status
No longer recruiting

Registration date
14/04/2020

Overall study status
Completed

Last Edited
23/08/2022

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.
In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of April 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.
Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.
The WHO has declared the current COVID-19 outbreak to be a pandemic and therefore a Public Health Emergency of International Concern. It is important to rapidly gain a better understanding of SARS-CoV-2 infection and the early signs of COVID-19 in order to reduce its spread.
The Ava bracelet is a a device worn like a watch that sends information to a smartphone app. It was designed to identify the most fertile days in a woman's menstrual cycle. The device measures skin temperature, pulse, breathing rate and blood flow and therefore might be able to detect the early signs of COVID-19, such as fever. It can also measure movement and might be able to detect a cough before a person is aware that they have started coughing more frequently. This means the Ava device could be useful in screening people who might have been exposed to coronavirus, but don't have any symptoms of infection. This study aims to investigate how the information collected by the device could be used to calculate how likely it is that a person has coronavirus infection and perhaps how severely they will be affected.

Who can participate?
The researchers will initially invite people who participated in a previous study started in 2010 to

participate in the first part of this study. The previous study recruited healthy adults aged 25-41 years who live in Liechtenstein. These people are aged 35-51 years in 2020. If possible, the researchers aim to recruit other people living in Liechtenstein to the second part of the study.

What does the study involve?
The participants will wear the Ava device every night throughout the study. They will be asked every month whether they have had COVID-19 or any symptoms that might relate to COVID-19. If there are COVID-19 specific symptoms, participants will be asked to provide a blood sample that will be tested undergo for COVID-19 virus and antibodies. All study participants will be asked to provide a blood sample at the end of the study to investigate whether they have SARS-CoV-2 antibodies.

What are the possible benefits and risks of participating?
There is minimal risk associated with using a wearable bracelet employing non-invasive monitoring, providing information and blood sampling. Benefit for the participants include the contribution in the development of an algorithm for early detection of COVID-19. Since participants may keep their bracelet after the study, participants might potentially benefit directly from an algorithm that detects early signs of COVID-19 or other viral infections.

Where is the study run from?
labormedizinisches zentrum Dr. Risch (Liechtenstein)

When is the study starting and how long is it expected to run for?
March 2020 to December 2021

Who is funding the study?
The government of Liechstenstein, the royal family of Liechtenstein and the HANELA Foundation (Switzerland)

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1.2

Study information

Scientific Title
Defining the role of a fertility bracelet for early recognition and monitoring of COVID-19 in Liechtenstein: an observational study (COVI-GAPP)

Acronym
COVI-GAPP

Study objectives
The WHO has declared the current coronavirus (COVID-19) outbreak to be a pandemic and therefore a Public Health Emergency of International Concern. It is crucial to rapidly gain a better understanding of the newly identified virus, especially in relation to potential clinical and public health measures that can be immediately used to improve patients' health and/or contain the spread of COVID-19. In particular, development of early and reliable detection of COVID-19 carriers and symptomatic individuals suspected of COVID-19 infection is needed. We are proposing to test the utility of a CE marked, marketed medical device that can continually track changes in physiological parameters in detecting early signs of a COVID-19 infection. In particular, the device's ability to register increases in physiological parameters associated with

fever (e.g., resting pulse rate, breathing rate, and skin temperature, movements) could render it an ideal candidate during screening point of care (POC), both for potential COVID-19 infections in asymptomatic, exposed users and asymptomatic users unsure of their exposure status. We aim to develop an algorithm based on monitoring data allowing for early prediction of development of COVID-19 as well as early recognition of severity of COVID-19 disease.
We intend to conduct the COVI-GAPP study in a first phase by recruiting study participants from the GAPP-study, which has been started in 2010 in the principalitiy of Liechtenstein in order to study the development of cardiovascular risk factors (https://doi.org/10.4414/smw.2013.13728) . The GAPP-study is a population based national cohort including 2170 study participants aged 25 to 41 at baseline. This number relates to about 32% of the whole population. The study participants are now 35 to 51 years old. The mean age of COVID-19 affected person in LIechtenstein currently is 43 years. In a second phase we want to open recruitment to other inhabitants of the principality of Liechtenstein ending up with a total of 5000 participants.
We hypothesize that by monitoring temperature, breath rate, pulse rate, and movements, it is possible to predict the occurrence of COVID-19 infection. In detail, we hypothesize, that temperature will increase due to inflammation/infection; breath rate will increase due to subclinical affection of lungs by COVID-19; heart rate variability as an indicator of stress will be diminished as a consequence of infection also reflecting severity of infection. Further, we anticipate that registration of characteristic movements also allows us to recognize cough. Fever, breathing problems, and cough are all clinical cornerstones in the diagnosis of COVID-19 infection. We further hypothesize that the alterations in measured parameters precede the occurrence of clinical symptoms. With this, it would be possible allow for early isolation of affected individuals, and subject patients to appropriate healthcare resources as early as possible. In order to achieve the aims of the study, we will develop an algorithm by means of a big data and machine learning approach.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/04/2020, the Cantonal Ethics Committee Zurich (Stampfenbachstrasse 121, CH-8090 Zurich, Switzerland; +41 43 259 79 70; Info.KEK@kek.zh.ch), ref: 2020-00786

Study design
Single-center observational study

Primary study design
Observational

Study type(s)
Diagnostic

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

Interventions
In a first phase, participants (n=2170) of the population-based GAPP study (https://doi.org/10.4414/smw.2013.13728) will be contacted to be recruited for the COVI-GAPP study. After a first phase of including participants from the GAPP study, we eventually might attain a sample size of 5000 participant by opening the inclusion criteria by onboarding additional participants residing in Liechtenstein. The second phase is depending on obtaining the funding.

Participants will be asked to use a wearable device called the AVA bracelet (https://www.avawomen.com) during the night until the study is terminated. Temperature, breath rate, pulse rate and movements are recorded. Information on COVID-19-specific health status is collected at study start and symptomatic patients will be diagnosed for COVID-19, as recommended by national guidelines. At the end of the study blood will be drawn for serological analysis of anti-SARS-CoV2 antibodies.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Occurrence of COVID-19 infection, as assessed by clinical signs, serology and/or RT-PCR testing. Date of occurrence, clinical symptoms and laboratory results will be collected. The endpoints will be collected by periodic monthly reports obtained on questioning the study participants. Participants and the treating healthcare institutions will be contacted to obtain respective information.

Key secondary outcome(s))
1. Severity of COVID-19 infection assessed using the following outcome measures. Participants and the treating healthcare institutions will be contacted to obtain respective information.
1.1. Hospitalization needed within 30 days of COVID-19 diagnosis (including timing)
1.2. ICU admission within 30 days of COVID-19 diagnosis (including timing)
1.3. Use of mechanical ventilation within 30 days of COVID-19 diagnosis (including timing)
1.4. Participant-reported health status up to 60 days after COVID-19 diagnosis (including timing)
1.5. COVID-19-related mortality up to 60 days after COVID-19 diagnosis (including timing)
1.6. Viral load assessed using quantitative RT-PCR at onset of clinical symptoms compatible with COVID-19
1.7. Quantitative immunoassay results of COVID-19-specific laboratory markers (including timing)
1.8. Presence of other respiratory pathogens in COVID-19-negative participants if available at 60 days after clinical symptoms (including timing)
1.9. Further healthcare contact of patients tested negative for COVID-19 up to 60 days after symptoms compatible with COVID-19 (including timing)

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Resident in Liechtenstein
2. Aged 35-51 years

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Aged under 18 years
2. Inability to provide informed consent

Date of first enrolment
14/04/2020

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
Liechtenstein

Study participating centre
labormedizinisches zentrum Dr. Risch
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Sponsor information

Organisation
labormedizinisches zentrum Dr. Risch

Funder(s)

Funder type
Government

Funder Name
Government of the principality of Liechtenstein

Funder Name
House of Liechtenstein

Funder Name
HANELA-Stiftung

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/06/2022	23/08/2022	Yes	No
Participant information sheet	Participant information sheet version 1.1	11/11/2025	11/11/2025	No	Yes
Protocol file		06/04/2020	23/08/2022	No	No