beReady study: A study to identify potential healthy volunteers eligible for early phase vaccine trials in the context of pandemic preparedness

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- To identify healthy volunteers that are able and willing to participate in future vaccine trials.- To install a pool of healthy volunteers ready to participate in vaccine research for infectious diseases.- To accelerate the set- up phase and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON55932

Source
ToetsingOnline

Brief title
beReady study

Condition

- Other condition

Synonym
Testing health status to be ready for a vaccine trial

Health condition

Testing health status

Research involving

Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: CHDR funded study

Intervention

Keyword: Healthy volunteers, SAR-CoV-2, Vaccin

Outcome measures

Primary outcome

Primary endpoint of this study is to install a pool of healthy volunteers who

are eligible and ready to participate in vaccine trials.

Secondary outcome

N.a.

Study description

Background summary

Vaccines are considered to be the best defence against emerging infectious diseases; however, the development of new vaccine is a lengthy process. In December 2019 the outbreak of the novel coronavirus (SARS-CoV-2) and earlier outbreaks of viruses such as SARS, MERS and Ebola have demonstrated that there is a societal responsibility to accelerate clinical vaccine development.
After vaccine discovery and preclinical research, new vaccines need to be tested in healthy volunteers to assess immunogenicity, safety, and tolerability. Clinical trials are considered the rate-limiting step in vaccine development. Normally, several months may be required for the set-up of a first-in-human vaccine trial with a new vaccine. We simply cannot afford to take this long to prepare the society for future emergencies caused by infectious diseases. It is therefore of essence to develop novel vaccines against rising infectious diseases rapidly.
To reduce the start-up time of first-in-human trials in outbreak setting and accelerate early clinical vaccine trial development, we propose a study to identify eligible healthy volunteers that could participate in future vaccine trials and/or are willing to donate blood for (preclinical) vaccine research

purposes. We suggest installing a dedicated pool of healthy volunteers who are available and ready to be enrolled and dosed within a short period of time. Thus, CHDR will maintain a pre-screened pool of eligible healthy volunteers, ready to participate in a clinical vaccine trial at any moment thereby enhancing pandemic preparedness. This approach will lead to important reductions in time to protect the general public against the global spread of infectious diseases such as SARS-CoV-2, and also other emerging infectious diseases.
The key concept to install the pool of healthy volunteers ready for vaccine trials is described in this protocol. Furthermore, the objective of the beReady protocol is also to make it possible to screen for community*s background immunity that is often required for setting up future vaccine trials or for the validation of controlled human infection models (CHIMs) to evaluate vaccine*s efficacy.
Yet, no details on the future investigational vaccine are available and are therefore not described in this protocol. At the time of a vaccine trial to be executed, a detailed clinical study protocol will be written and submitted for ethical review together with the necessary (updated) research files. The 'beReady volunteers* have the opportunity to participate in a future study under a dedicated informed consent document to be written.

Study objective

- To identify healthy volunteers that are able and willing to participate in future vaccine trials.
- To install a pool of healthy volunteers ready to participate in vaccine research for infectious diseases.
- To accelerate the set- up phase and ultimately the overall time to complete vaccine trials.
- To screen for background immunity for certain pathogens, required for the purpose of setting up future vaccines studies or for the validation of CHIMs, necessary to evaluate vaccine*s efficacy.

Study design

This is a program to recruit healthy volunteers, assess their eligibility and install a cohort of eligible candidates prior to enrollment into a vaccine trial. The study is designed to facilitate rapid set-up of a clinical vaccine trial, by asking healthy volunteers to be on a stand-by mode in case of an urgent outbreak/pandemic. The beReady study will make it possible to screen for background immunity for certain pathogens by taking serum samples of beReady subjects for antibody analysis. Assessing the background immunity in the population may be necessary for setting up future vaccine trials of for the validation of controlled human infection models.
This study has three parts depending on what information is needed for a future clinical vaccine study: The three parts are described below. Volunteers

will always participate in Part 1. Part 2 and 3 will only be operational if more information on general health status is required or blood samples are needed.
- Part 1: a questionnaire regarding general medical status will be sent per e-mail to volunteers that are interested to take part in the beReady pool.
- Part 2: if required, a medical staff member of CHDR will contact the participants who showed interest in participation for additional questions regarding medical history and general health status.
- Part 3: ambulant visit to CHDR for serum sample collection (i.e. including but not limited to antibody titers for - for example - screening for background immunity), not exceeding 100 mL per blood donation and/or screening activities including, but not limited to, physical examination, BMI and blood sample for safety lab
To take part in the beReady pool, subjects should give consent for all parts. Participants will be asked to contact CHDR if there are changes in their health status. Subjects give consent for a period of five years, hereafter the consent recedes. In case of prolongation a new informed consent will be signed.

Study burden and risks

The subjects will be asked to participate in an investigational vaccine study. This option is voluntary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Part 1 (e-mail questionnaire)
1. Healthy male or female subjects, >= 18 years of age;
2. Body mass index (BMI) >= 18.0 and < 32.0 kg/m2;
3. Willing to stay available and share availability for vaccine trial participation;
4. Signed informed consent prior to any study- related procedures.

Part 2 (Phone screening):
1. Healthy male or female subjects, >= 18 years of age. Healthy status is defined by absence of evidence of any active or chronic disease following a detailed medical history;
2. Body mass index (BMI) >= 18.0 and < 32.0 kg/m2;
3. Willing to stay available and share availability for vaccine trial participation;
4. Signed informed consent prior to any study- related procedures.

Part 3 (On site screening)
1. Healthy male or female subjects, >= 18 years of age. Healthy status is defined by absence of evidence of any active or chronic disease following a detailed medical and history;
Subjects 65 years of age and older: in the investigator*s clinical judgment, participant must be either in good or stable health. Participant may have underlying illnesses, as long as the symptoms and signs are medically controlled and not considered to be comorbidities related to an increased risk of severe COVID-19, except for smoking, which is allowed (see also exclusion criterion 6).
2. Body mass index (BMI) >= 18.0 and < 32.0 kg/m2;
3. Willing to stay available and share availability for vaccine trial participation;
4. Signed informed consent prior to any study- related procedures.

Exclusion criteria

Part 1 (e-mail questionnaire):
1. History of abuse of addictive substances (alcohol, illegal substances) or current use of more than 21 units alcohol per week, drug abuse, or regular user of sedatives, hypnotics, tranquillizers, or any other addictive agent;
2. History of anaphylaxis or other significant adverse event following immunization.

Part 2 (Phone screening):
1. History of abuse of addictive substances (alcohol, illegal substances) or current use of more than 21 units alcohol per week, drug abuse, or regular user of sedatives, hypnotics, tranquillizers, or any other addictive agents;
2. History of anaphylaxis or other significant adverse event following immunization;
3. Evidence of any active or chronic disease or condition that could interfere with, the conduct of a study with a candidate vaccine, or that would pose an unacceptable risk to the subject in the opinion of the investigator (following a detailed medical history);
4. Prior receipt of immunoglobulins or vaccinations that is likely to impact interpretation of study outcomes.

Part 3 (On site screening)
1. Evidence of any active or chronic disease or condition that could interfere with, the conduct of a study with a candidate, or that would pose an unacceptable risk to the subject in the opinion of the investigator (following a detailed medical history);
2. History of anaphylaxis or other significant adverse event following immunization;
3. Prior receipt of immunoglobulins or vaccinations that is likely to impact interpretation of study outcomes;
4. Participation in an investigational drug study;
5. History of abuse of addictive substances (alcohol, illegal substances) or current use of more than 21 units alcohol per week, drug abuse, or regular user of sedatives, hypnotics, tranquillizers, or any other addictive agent;
6. Heavy smokers who normally consume more than 5 cigarettes a day. Smokers will be defined as any subject who reports tobacco use;
7. Any confirmed significant allergic reactions (urticaria or anaphylaxis) against any drug, or multiple drug allergies;
8. History of bleeding disorder (e.g. factor deficiency, coagulopathy, or platelet disorder requiring special precautions), significant bleeding or bruising following intramuscular injections or vena punctures;
9. Loss or donation of blood over 500 mL within three months (males) or four months (females) prior to enrollment in the healthy volunteer pool or intention to donate blood or blood products during the stand-by participation in a vaccine trial;

10. Any known factor, condition, or disease that might interfere with treatment compliance, study conduct or interpretation of the results such as drug or alcohol dependence or psychiatric disease.

Note that not for all future vaccine trials all the above-described exclusion criteria are required. Then, only a subset of exclusion will be taken. No additional assessments than required for the above-described exclusion criteria will be performed.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-04-2020
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	T.b.d.

Ethics review

Approved WMO

Date:	28-05-2020
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO Date:	04-08-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-08-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2020-002014-40-NL
CCMO	NL73866.000.20