Trial Description

Title

Safety profile of COVID-19 vaccines and the comparison to COVID-19 symptomatology

Trial Acronym

ImpfSurv

URL of the trial

https://www.charite.de/service/klinische_studien_detail/item/studien_detail/impfsurv/

Brief Summary in Lay Language

Vaccination course, course of a COVID-19 disease, as well as long-term consequences of a Corona infection are to be compared with the vaccination reactions of vaccinated and health impairments of non-vaccinated persons.

Brief Summary in Scientific Language

Vaccination course, course of a COVID-19 disease, as well as long-term consequences of a Corona infection are to be compared with the vaccination reactions of vaccinated and health impairments of non-vaccinated persons. For this purpose, an online vaccination-survival questionnaire is used in this observational study, which records physical complaints after vaccination, COVID-19 disease and general complaints.

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00024800**
- Date of Registration in DRKS: **2021/04/26**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EA1/057/21 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

- Other Secondary-ID: **3000242 (Zenrales Studienregister der Charité)**

Health condition or Problem studied

- ICD10: **Z20.8 - Contact with and exposure to other communicable diseases**
- ICD10: **U07.1 - Emergency use of U07.1**

Interventions/Observational Groups

- Arm 1: **Longitudinal observational study without intervention with the aim of building a database of symptoms of COVID-19 vaccination or COVID-19 disease or general complaints of subjects not vaccinated against or not suffering from COVID-19 at baseline and over the course of two years.**

  All subjects between 18 and 105 years of age who provided written informed consent will be included.

  Implementation: study participants will complete an online survey. The first survey of all subjects will be conducted at the time of the subject's initial voluntary enrollment via the online survey. Follow-up: In the form of a follow-up survey, interviews are conducted monthly for the first 6 months after the initial survey and then every 3 months for a period of 2 years.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
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Allocation: **Single arm study**

- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary objective parameter is to assess adverse vaccination reactions in COVID-19 vaccinated individuals compared to the adverse health effects in COVID-19 diseased and non-diseased individuals, respectively. The target parameter will be collected using a newly developed online questionnaire.

Secondary Outcome

All other analyses involving predictors influencing vaccination responses or general or health impairments resulting from COVID-19 disease are exploratory.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Charité Universitätsmedizin Berlin, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2021/04/26**
- Target Sample Size: **7800**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **105 Years**

Additional Inclusion Criteria

Included in the study are:
- Subjects 18 years of age and older
- Subjects who have received COVID-19 vaccination and have not had COVID-19.
- Subjects who have received COVID-19 vaccination and have had COVID-19.
- Subjects who had COVID-19 and were not vaccinated
- Subjects who have not had COVID-19 disease.
- Ability to give consent and signed informed consent form.

Exclusion criteria

Subjects without an understanding of the German language will be excluded from the study. Participants will also be excluded if they are participating or have participated in another (clinical) study that has not been completed 3 months prior to study participation.

Addresses

- **Primary Sponsor**

  Charité - Universitätsmedizin Berlin
  10117 Berlin
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Software AG
64297 Darmstadt
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

* *This entry means the parameter is not applicable or has not been set.*

*** *This entry means that data is not displayed due to insufficient data privacy clearing.*