PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

SARS-CoV-2 serology in HIV PrEP users during the COVID-19 pandemic: THE PREP-CO STUDY

Trial Acronym

PrEP-Co

URL of the trial

[---]*

Brief Summary in Lay Language

[---]*

Brief Summary in Scientific Language

To investigate to prevalence and seroconversion rate of SARS-CoV-2 antibodies in a German cohort of MSM using HIV PrEP, Germany, over a time period of one year following the first outbreak of the covid pandemic.

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

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00022403**
- Date of Registration in DRKS: **2020/07/15**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **292/20 S , Ethik-Kommission der Fakultät für Medizin der Technischen Universität München**

Secondary IDs

Health condition or Problem studied

- Free text: **HIV-PrEP**
- Free text: **STD**
- ICD10: **Z29.21 - [generalization Z29.2: Other prophylactic chemotherapy]**

Interventions/Observational Groups

- Arm 1: **Performance of SARS-CoV-2 serology**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Other**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Seroconversion rate pointprevalence of SARS-CoV-2 antibody during the time of this study.

Secondary Outcome

- Pointprevalence of SARS-CoV-2 antibodies at baseline.
- Pointprevalence of SARS-CoV-2 antibodies at follow-up visits.
- correlation of the seroprevalence and/or seroconversion of SARS-CoV-2 positivity with sexual behaviour and other sexual transmitted diseases (STDs), such as syphilis, N. gonococcae, M. genitalium, C.trachomatis or HIV.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinikum Rechts der Isar der TU München, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/05/18**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- MSM reporting PrEP-use within last 90 months prior to screening visit
- Written informed consent.
- Age ≥18 years.

Exclusion criteria

Persons with any kind of dependency on the investigator.

Addresses

- **Primary Sponsor**

  Klinikum Rechts der Isar
  Ismaninger Str 22

Primary Sponsor

Klinikum Rechts der Isar
Ismaninger Str 22
81675 München
Germany

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

■ **Contact for Scientific Queries**

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■ **Contact for Public Queries**

IZAR
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Germany

Telephone: **089/41402451**
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E-mail: **izar at mri.tum.de**
URL: **[---]***

Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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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.*