

Trial Description

Title

Clinical translational and epidemiological research project on SARS coronavirus 2 infection in during the COVID 19 pandemic children in Bavaria

Trial Acronym

COVID Kids Bavaria

URL of the trial

[---]*

Brief Summary in Lay Language

COVID KIDS BAVARIA is a Bavaria-wide study in which six children's hospitals from Bavarian universities take part. The aim of the study is to examine the role of children in the spread of COVID-19, the effects of school and kindergarten closings on the spread and the psychological effects of these interventions on toddlers and children in Bavaria. Kindergartens and schools are contacted and all children are invited to participate. Participation includes a detailed questionnaire and, in some of the subjects, a swab from the nasopharynx.

Brief Summary in Scientific Language

COVID KIDS BAVARIA is a prospective multicenter observational study with the aim to access the role of children in disease spread, the effect of school and kindergarten closures and the psychological impact of those interventions on infant and children in Bavaria.

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

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00022380**
- Date of Registration in DRKS: **2020/07/07**
- 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.: **20-538 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **U07.1 - Emergency use of U07.1**

Interventions/Observational Groups

- Arm 1: **Epidemiological, prospective, multicenter study. Examination of the spread of COVID-19 in primary schools and kindergartens in Bavaria. Examining the impact of prevention measures on the well being of children. Pilot phase with questionnaire and nasopharynx swab (COVID-19 PCR). Then phase 1-3 from September 2021 to April 2021 with questionnaire and nasopharynx swab (COVID-19 PCR). Final (4th) phase with testing of blood for SARS-CoV-2 antibodies for pupil and teacher of primary schools plus short questionnaire**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological study**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
-

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Purpose: **Other**

Assignment: **Single (group)**

Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Spread of COVID-19 in primary schools and childcare

Secondary Outcome

Impact of school and childcare closings on children's health

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- **University Medical Center LMU Klinikum, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/07/21**
- Target Sample Size: **14000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **0 Years**
- Maximum Age: **10 Years**

Additional Inclusion Criteria

Caregiver or child in one of the selected institutions

Exclusion criteria

People who do not belong to the selected institutions

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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80327 München
Germany**

Telephone: [---]*

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URL: [---]*

Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruiting started": [---]*
- Reason, if Reason for Recruiting Stop "Other": [---]*
- Study Closing (LPLV): [---]*
- Number of Participants in Germany after Recruiting complete: [---]*
- Total Number of Participants (all Sites worldwide) after Recruiting complete: [---]*

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.