



Trial Description

Title

Impact of indoor temperature on the vulnerable population of geriatric patients in the context of climate change - An analysis of pulmonologic and geriatric outcomes

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

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Brief Summary in Scientific Language

This observational trial will analyse the relation between critical events and heat. We will build a predictive temperature model for an outdoor-indoor-heat relation and associated risks.

Objective 1: Defining outdoor-indoor-relations for temperatures in patient rooms with and without air conditioning.

Objective 2: Analysis of critical events in association with heat. Analysis of incidence for COPD exacerbations, myocardial infarction, falls, stroke and others.

Organizational Data

- DRKS-ID: **DRKS00018692**
- Date of Registration in DRKS: **2019/10/09**
- 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.: **EA4/117/19 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs



Health condition or Problem studied

- Free text: **COPD exacerbation, pneumonia, acute coronary syndrom, synkope, renal failure, electrolyte imbalances, stroke, fall, death.**
- ICD10: **J44.1 - Chronic obstructive pulmonary disease with acute exacerbation, unspecified**
- ICD10: **J18.9 - Pneumonia, unspecified**
- ICD10: **I24.9 - Acute ischaemic heart disease, unspecified**
- ICD10: **R55 - Syncope and collapse**
- ICD10: **N19 - Unspecified kidney failure**
- ICD10: **E87.8 - Other disorders of electrolyte and fluid balance, not elsewhere classified**
- ICD10: **I64 - Stroke, not specified as haemorrhage or infarction**
- ICD10: **R99 - Other ill-defined and unspecified causes of mortality**

Interventions/Observational Groups

- Arm 1: **Outdoor- and indoor-temperatures are recorded in patient rooms and correlated to critical incidents (cf. health condition studied). In a first step patients are enrolled in the study and after hospital discharge, an analysis of hospital patient records is performed. In this study no additional diagnostic test or additional treatment is performed.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- 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

COPD exacerbation, pneumonia, acute coronary syndrom, synkope, renal failure, electrolyte imbalances, stroke, fall, death. Patient transport to intermediate or intensive care unit, dropout of treatment/early discharge, extension of hospital

stay.

Secondary Outcome

[---]*

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Charité Universitätsmedizin Berlin, Berlin**
- Medical Center **Evangelisches Geriatrie Zentrum Berlin, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/10/01**
- Target Sample Size: **250**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **60 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

-Hospitalised, geriatric patient. (All patients of a geriatric ward/clinic are in line with the inclusion criteria). More specific inclusion criteria are not defined.

Exclusion criteria

-Patients not able to give consent, or patients of who the legal custodian refuses the inclusion of his client, patients that withdraw consent.

Addresses

■ **Primary Sponsor**

**Charité Campus Charité Mitte
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■ **Contact for Scientific Queries**

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■ **Collaborator, Other Address**

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Sources of Monetary or Material Support

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

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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.