Trial Description

Title

Treatment of Sars-CoV2 infections (Covid-19) with valsartan vs placebo, a three-armed randomized, partly blinded trial

Trial Acronym

CovidVal01

URL of the trial

http://www.covidval.de

Brief Summary in Lay Language

The COVIDAL trial includes the randomized switch from ACE inhibitors to angiotensin receptor blockers (ARBs) and the use of ARBs versus placebo for SARS-COV-2 infection. The background to this study is unconfirmed speculation about the effect of ACE inhibitors and ARBs in Covid-19. These drugs should not be discontinued out of speculative caution. However, there are well-founded mechanistic considerations that ARBs are more useful than ACE inhibitors in terms of their Covid-19 effect, while having the same efficacy against hypertension, heart and kidney failure.

Therefore, by switching from ACE inhibitors to ARBs or adjusting to ARBs, the relationship between these drugs and corona infection is being investigated. The aim is to analyse which individual patients could benefit from switching from ACE inhibitors or adjusting to ARBs.

Brief Summary in Scientific Language

Since there is no drug therapy available to treat the currently pandemic SARS-Cov2 virus, available therapeutic principles must be examined for their suitability. Due to the interrelationship of the virus entry mechanism with the ACE 2 receptor, there are complex considerations on the efficacy and speculations on the harmfulness of ACE inhibitors and angiotensin receptor blockers. Due to the highly evident effects in renovascular and cardiovascular diseases, such drugs should not be discontinued out of speculative caution. There are, however, well-founded mechanistic considerations that, while having the same efficacy in the reno- and cardiovascular area, angiotensin receptor blockers rather do not involve lung damage and covid-19 acceleration. Therefore, a controlled trial will be conducted, which includes the randomized switch from ACE inhibitors to angiotensin receptor blockers in pretreated patients and the use of angiotensin receptor blockers de novo versus placebo in patients not previously treated with ACE inhibitors or angiotensin receptor blockers. All patients with positive SARS-COV2 detection should be included. The patient integration will be done digitally via a messenger system. The randomized test medication will be sent by post to outpatients. Inpatients will be treated by the study department of the trial site during their stay.

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00021732**
- Date of Registration in DRKS: **2020/06/10**
- 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.: **EK-AMG-MO-1/20-1 , Ethikkommission bei der Sächsischen Landesärztekammer**

Secondary IDs

- EudraCT-No.
(for studies acc. to Drug Law): **2020-001431-27**

Health condition or Problem studied

- Free text: **Covid-19**

Interventions/Observational Groups

- Arm 1: **Patients not pretreated with ACE inhibitors or AT1 antagonists: Valsacor 80 mg 1-0-1 (target dose if well tolerated, starting dose 0-0-1) vs. P-tablets Lichtenstein white 1-0-1 (target dose if well tolerated, starting dose 0-0-1)**
- Arm 2: **Patients pretreated with ACE inhibitors: Valsacor 80 mg 1-0-1 (target dose if well tolerated, starting dose: equivalent of previous medication with ACE inhibitor) vs. ramipril 5 mg (or equivalent) 1-0-0 (target dose if well tolerated, starting dose: previous ACE inhibitor medication or ramipril equivalent)**
- Arm 3: **Patients pretreated with AT1 antagonists: Valsacor 80 mg (or equivalent) 1-0-1 (target dose with good tolerability, starting dose: previous AT1 antagonist medication or valsartan equivalent)**

Characteristics

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Study Type: **Interventional**

- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Placebo, Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **Yes**

Primary Outcome

combined clinical improvement (7-category ordinal scale of clinical Status or Hospital discharge), daily assessment

Secondary Outcome

Secondary endpoints are collected post-hoc according to the availability of routine data. Mainly respiratory indices (Horovitz), virus load or PCR results, ventilation frequency, duration of hospitalisation and death are considered

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Klinikum St. Georg gGmbH, Leipzig**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/06/30**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**

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- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Patients aged over 18 years with given consent, first positive Sars-Cov2 detection within the last three days
- Patients with pre-existing chronic renal insufficiency in any degree of severity
- Patients of both gender

Exclusion criteria

- intolerance to RAS-I and ARB
- Contraindications against ACE/ARB according to current clinical standard
- History of falls (more than 2 falls in the last 8 weeks)
- Symptomatic hypotension (i.e. blood pressure < 100 mmHg systolic and/or 50 mmHg diastolic together with hypotensive symptoms)
- Acute renal failure from stage 2
- pregnancy

Addresses

- **Primary Sponsor**

Klinikum St. Georg gGmbH
Delitzscher Straße 141
04129 Leipzig
Germany

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

- **Contact for Scientific Queries**

Klinikum St. Georg gGmbH, Klinik für Infektiologie/Tropenmedizin, Nephrologie und Rheumatologie
Mr. Prof. Dr. Joachim Beige
Delitzscher Str. 141
04129 Leipzig
Germany

Telephone: **03419094056**
Fax: **[---]***
E-mail: **joachim.beige at sanktgeorg.de**

Contact for Scientific Queries

Klinikum St. Georg gGmbH, Klinik für Infektiologie/Tropenmedizin, Nephrologie und Rheumatologie
Mr. Prof. Dr. Joachim Beige
Delitzscher Str. 141
04129 Leipzig
Germany

Telephone: **03419094056**
Fax: **[---]***
E-mail: **joachim.beige at sanktgeorg.de**
URL: **[---]***

■ **Contact for Public Queries**

Klinikum St. Georg gGmbH, Klinik für Infektiologie/Tropenmedizin, Nephrologie und Rheumatologie
Mr. Prof. Dr. Joachim Beige
Delitzscher Str. 141
04129 Leipzig
Germany

Telephone: **03419094056**
Fax: **[---]***
E-mail: **covidval at sanktgeorg.de**
URL: **[---]***

Sources of Monetary or Material Support

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

Klinikum St. Georg gGmbH
Delitzscher Straße 141
04129 Leipzig
Germany

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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.*