Do Angiotensin Receptor BLOCKers have beneficial effect on the disease course of COVID-19 infection in high risk or elderly patients in an early phase

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Objective: To assess whether angiotensin receptor blocker (ARB) use is beneficial in the early phase of the disease, to prevent lung oedema and damage in high risk patients with a proven COVID-19 infection.

Ethical review	Not approved
Status	Will not start
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON50002

Source
ToetsingOnline

Brief title
LOCK-COVID-19

Condition

- Viral infectious disorders

Synonym
SARS-CoV-2; COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: overige zorg verzekeraars

Intervention

Keyword: angiotensin receptor blockers, COVID-19, Elderly

Outcome measures

Primary outcome

Study endpoints: The primary outcome for this study is a combination of death

or hospital admission after 30 days.

Secondary outcome

Secondary outcomes are time to reduce symptoms, such as fever, cough and

dyspnoe after 30 days.

Study description

Background summary

Recent research concerning the covid-19 virus causing a pandemic suggests that angiotensin-receptor blocking therapy could be clinically beneficial for Covid-19 infected patients, especially in an early phase. AT1R blockage by ARB therapy could be able to prevent the elevated angiotensine II expression, which is responsible for lung edema and damage in infected patients.

Study objective

Objective: To assess whether angiotensin receptor blocker (ARB) use is beneficial in the early phase of the disease, to prevent lung oedema and damage in high risk patients with a proven COVID-19 infection.

Study design

Study design: The Lock-covid-19 study is an open-label randomized controlled trial assessing the effect of ARB in an early phase on high risk covid-19 patients to prevent hospital admission and death, as compared to conventional therapy.

Intervention

Intervention: The intervention consists of Telmisartan 160 mg once daily, taken orally for 14 days. preceded by a 2 test doses, 12 hours apart.

Study burden and risks

Patients allocated to the interventional group will receive Telmisartan following standard practice in clinical setting for hypertension treatment. Common side effects are dizziness, headache, nausea and/or vomiting, cough, hyperkalaemia and hypotension. Liver and/or kidney failure, leukopenia and angioedema are severe, yet rare, side effects. Registered interactions of ARB*s are fluconazole, rifamycin and drugs elevating the potassium level. Since Covid-19 is a relatively new virus, we have yet to discover most of the etiology and physiology of the virus. Therefore, we cannot foresee any interactions or side effects for Covid-19 patients specifically.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age * 70 years of age or comorbidities such as chronic lung disease, cardiovascular disease, any solid or haematological malignancies, diabetes, hypertension, rheumatic disease, immune-deficiencies either by disease or by medication use or severe obesity (BMI * 35).
- Fever (a temperature of * 38,0 °C) or complaints of cough with or without dyspnoea
- AND at least one of these symptoms typical for SARS-CoV-2 infection such as:
o fatigue
o myalgia
o headache
o nausea, vomiting and diarrhoea
o loss of smell and/or taste.
- Positive PCR test or High suspicion of a SARS-COV-2 infection because of typical symptoms and the possibility that the individuals could have been infected.
- Being able to give written or verbal informed consent

Exclusion criteria

- Suffering from (symptomatic) hypotension
- Registered allergy to Telmisartan.
- Receiving Potassium supplement.
- Renal failure requiring dialysis therapy or (previous) kidney transplant
- Known liver disease or liver insufficiency
- Inability to comprehend patient information due to mental impairment such as dementia.
- life expectancy of less than 3 months

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	642
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Micardis
Generic name:	Temisartan
Registration:	Yes - NL outside intended use

Ethics review

Not approved

Date:	02-11-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2020-002343-32-NL
CCMO	NL74029.018.20