Countering Lung Damage in COVID-19 infection (CounterCovid) study

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Our hypothesis is that treatment with imatinib results in a reduction of the time to liberation from ventilation and supplemental oxygen and alive in Covid19.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23447

Bron
Nationaal Trial Register

Verkorte titel
CounterCovid19

Aandoening

Covid19 positive pneumonitis with need for hospital admission

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: AMC foundaition and VUmc Fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

time to liberation from ventilation and supplemental oxygen and alive during a 28day period after randomization

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Covid19 infection is characterized by hypoxemic respiratory failure, caused by extensive vascular leak and pulmonary edema early in the course of disease. Although there is no proven therapy to reduce viral replication in Covid19, recent studies from our department have discovered that the tyrosine kinase inhibitor imatinib reinforces the endothelial barrier and prevents vascular leak in inflammatory conditions, while leaving the immune response intact. We hypothesize that reversing vascular leak is an effective approach to reduce disease burden and consumption of medical resources.
Objective: To test whether treatment with oral imatinib reduce disease burden and consumption of medical resources.
Study design: A randomized, double-blind, placebo controlled, clinical trial.
Study population: Patients (>18years) with proven Covid19 infection, admitted to the hospital with hypoxemic respiratory failure (SaO2<92% or kPa<8 on room air), with a study population of 386 patients (193/arm).
Intervention (if applicable): The intervention group will receive a starting dose of 800mg oral imatinib, followed by 400mg od during 10 days. The control group will receive a similar dosing schedule with a placebo.
Main study parameters/endpoints: The main study parameter is the time to liberation from ventilation and supplemental oxygen and alive during a 28day period after randomization.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participation involves randomization to either the intervention or the placebo group. In both groups patients will undergo blood sampling at 9 time-points, at each time-point 1 or 4 tubes of 5mL will be drawn. Additional tests include a viral swab from the throat at 2 time-points, and an ECG at 5 time-points. Part of these interventions are part of routine care. Physical discomfort associated with participation involves swallowing of tablets, and side effects of the study medication, which are considered mild (predominantly gastro-intestinal discomfort). Anticipated benefits from the study medication involve faster recovery from Covid19 and a lower risk for ICU admission or death.

Doel van het onderzoek

Our hypothesis is that treatment with imatinib results in a reduction of the time to liberation from ventilation and supplemental oxygen and alive in Covid19.

Onderzoeksopzet

2

Onderzoeksproduct en/of interventie

Imatinib or placebo

Contactpersonen

Publiek

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Harm Jan Bogaard

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Wetenschappelijk

Amsterdam UMC, location VUmc
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age >18 years
- Hospital admission with proven SARS2-Covid19 infection
- Hypoxemic respiratory failure (SaO2 <92%, PaO2 <8kPa)
- Ability to give informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pre-existing chronic pulmonary disease, including:
 Known diagnosis of Interstitial Lung disease
 Former diagnosis of COPD 4 or FEV1<30%pred
 DLCO <45%
 Total lung capacity (TLC) < 60% of predicted
 Lung cancer with non-surgical treatment in last year
2. Home oxygen treatment
3. Pre-existing heart failure with a known left ventricular ejection fraction <40%
4. Active treatment of hematological or non-hematological cancer with targeted, immuno- or chemotherapy in the last year
4. Inability to provide informed consent

5. Any subject who had received any investigational medication within 1 month prior to the start of this study or who is scheduled to receive another investigational drug during the course of this study
6. Active liver disease, porphyria or elevations of serums transaminases >3 x ULN (upper limit of normal) or bilirubin > 1.5 x ULN
7. History or suspicion of inability to cooperate adequately.
8. White blood count < 4.0^109/l
9. Hemoglobin < 6.0 mmol/l
10. Thrombocytes < 100^109/l
11. Pregnant female subjects
12. Breastfeeding female subjects

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	31-03-2020
Aantal proefpersonen:	386
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	31-03-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8491
Ander register	METC VUMC : 2020.158

Resultaten