The role of renal function in the pharmacokinetics and safety of remdesivir in COVID-19 patients

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To determine the influence of renal function and renal replacement therapy on the pharmackinetics and safety of remdesivir in COVID-19 patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON51092

Source
ToetsingOnline

Brief title
Remdesivir in renal impairment

Condition

- Viral infectious disorders

Synonym
Coronavirus Disease 2019, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: het HagaZiekenhuis en de Apotheek Haagse Ziekenhuizen

Intervention

Keyword: pharmacokinetics, remdesivir, renal function, safety

Outcome measures

Primary outcome

- Remdesivir and metabolite (GS-44152) plasma 24-hours area under the curve

- Remdesivir and metabolite half-life

- Remdesivir and metabolite through concentration

Secondary outcome

Incidence of adverse events

Clinical course

Study description

Background summary

Though it is not contra-indicated, the SPC warns against the use of Veklury (Remdesivir) in patients with an eGFR *30 ml/min as data upon benefit and risks are lacking. However, based on preclinical data and data about the toxicity of SBECD (an excipient in Veklury) it is reasonable to assume that a short course of remdesivir, such as is prescribed for the treatment of coronavirus disease 2019 (COVID-19), is safe in patients with severely impaired renal function. Up to date only limited pharmacokinetic and clinical data to confirm this statement are available. The medical need and increased use of remdesivir in the COVID-19 pandemic presents an opportunity to investigate the pharmacokinetics and safety of remdesivir in these patients.

Study objective

To determine the influence of renal function and renal replacement therapy on the pharmackinetics and safety of remdesivir in COVID-19 patients.

Study design

The study is an observational, prospective, cohort study. Initiation of remdesivir is not a part of this protocol. The pharmacokinetics will be

compared between three groups. The first group consists of COVID-19 patients without severely decreased renal function (eGFR > 30 ml/min), the second of patients with severely reduced renal function (eGFR * 30 ml/min) and the third of patients receiving renal replacement therapy. Blood samples to investigate the pharmacokinetics will be drawn on day 1 and 5 (or the day after the final gift). The safety profile of remdesivir will be studied during and after the treatment with remdesivir by monitoring the occurrence of AEs.

Study burden and risks

The study is an observational non-interventional study with blood sampling on the first and fifth day of therapy. The risks for patients due to extra blood sampling is regarded negligible. To further reduce complications, sampling procedures will be performed by health care professionals who are trained in these procedures.

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

- diagnosed with COVID-19 by polymerase chain reaction (PCR) on exudate obtained by oral- nasopharyngeal swab
- admitted to the Haga hospital (ward or ICU)
- prescribed intravenous remdesivir
- The subject has signed and dated a written informed consent.

Exclusion criteria

- is expected to be transferred to another hospital during remdesivir therapy
- The treating physician deems the subject unfit to participate in this study.
- Pregnancy
- Patients who choose to forego dialysis and prefer to be managed conservatively

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2021
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	18-01-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	07-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL75815.058.20