Remdesivir: Critical Clinical Appraisal for COVID 19 Treatment

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ABSTRACT

Remdesivir is presently been considered as 'molecule of hope' to curb the menace of COVID19. Non-availability of any USFDA approved drug has led to several attempt of drug-repurposing and development of new therapeutic molecules. However, Remdesivir has been found to be effective against a broad range of virus including SARS, MERS and COVID 19 through in-vitro studies. Several clinical research attempt are presently being conducted showing promising result yet not conclusive. This review summarized all such clinical trials to critically appraise the usage of Remdesivir against COVID 19 along with the publications related to the results of the clinical studies. The present regulatory aspect i. e. Emergency Use Authorization (EYA) and information of molecule and plausible mechanism is also dealt.

Introduction

Since the outbreak of COVID 19, there has been extensive attempt from every sphere to come up with a suitable medicine for treatment purpose. However, till date there has been no single approved medicine for COVID 19 treatment [1] though several of them are in clinical trial and are showing promising result. Remdesivir is presently the frontrunners among the drug of choice for the treatment of COVID-19 as evidenced from clinical trials. However, there is no consolidated critical clinical summery on the activity and performance of Remdesivir in clinical settings. This article approaches a critical appreciation on the drug based on clinical evidences which is essential in present context.

About the molecule

Remdesivir is chemically known as 2-ethylbutyl (2S)-2-[[[(2R,3S,4R,5R)-5-(4-aminopyrrolo[2,1-f][1,2,4]triazin-7-yl)-5-cyano-3,4-dihydroxyoxolan-2-yl]methoxy-phenoxyphosphoryl]amino]propanoate (IUPAC Name) with a molecular weight of 602.6 g/mol. Remdesivir, or GS-5734 is an ATP analogue having medicinal property and used as drug [2]. The structure of Remdesivir is shown in ▶ **Fig. 1**.

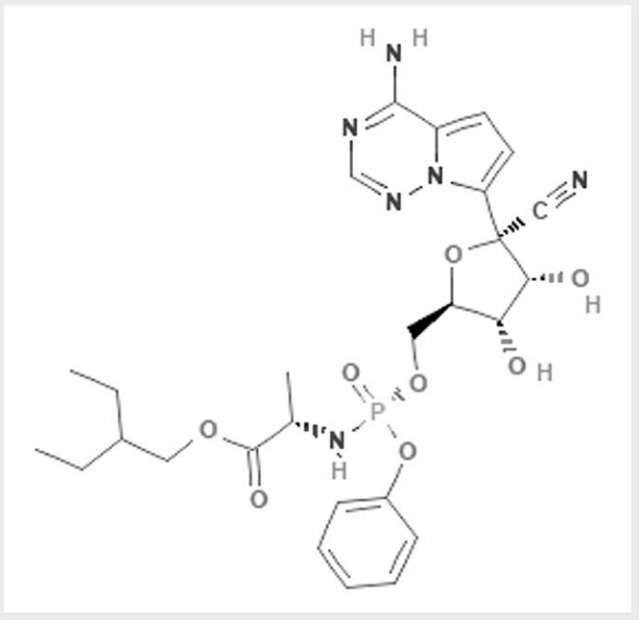
Remdesivir as Drug

Remdesivir (GS5734) was developed by Gilead Science, an American biopharmaceutical company as a molecule for potential treatment to Hepatitis C in 2009, but failed [3]**.** Since 2016 the molecule Remdesivir gained popularity as drug because of its application against Ebola virus [4]. It has also shown good efficacy against SARS CoV-2 (COVID19) through in-vitro studies [5] that has led to the popularity of the drug among medical practitioners and scientific community. Remdesivir is conserved as a broad spectrum antiviral drug. Remdesivir is a prodrug of an adenosine triphosphate (ATP) analog acting against RNA viruses [6].

USFDA Approval

The drug Remdesivir is not approved by USFDA. However, on May 1st 2020, the USFDA has provided Emergency Use Authorization (EUA) and permits the emergency use of the drug for the treatment

of suspect and laboratory confirmed COVID 19 case in adult and children hospitalized with severe disease [7]. The EPA allows Remdesivir to be distributed and administered intravenously by health care providers, as appropriate for the treatment of COVID-19. Based on the evaluation of EUA and clinical evidence available, considering the non-availability of any drug or treatment options for COVID-19, Remdesivir is assumed to be effective. The fact sheet provides detailed guidelines in this regard. EUA is provided to Gilead Sciences Inc. that simultaneously carries out clinical trials.



▶ **Fig. 1** Chemical Structure of Remdesivir.

EUA is issued under section 564 (FD&C Act) was amended by the Project Bioshield Act of 2004 and was further amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), the 21st Century Cures Act of 2016, and Public Law 115–92 of 2017 [8].

Probable mechanism against COVID19

Remdesivir is a prodrug of an adenosine triphosphate (ATP) analog and its triphosphate form (RDV-TP) is known to inhibit the synthesis of viral RNA by delayed chain termination method [5]. A probable molecular mechanism is deciphered that the RDT-TP binds with RNA dependent RNA Polymerase [6] and forms complex with the viral RNA and ATP to inhibit RNA synthesis [9]. ▶ **Fig 2** summarizes the plausible mechanism of Remdesivir.

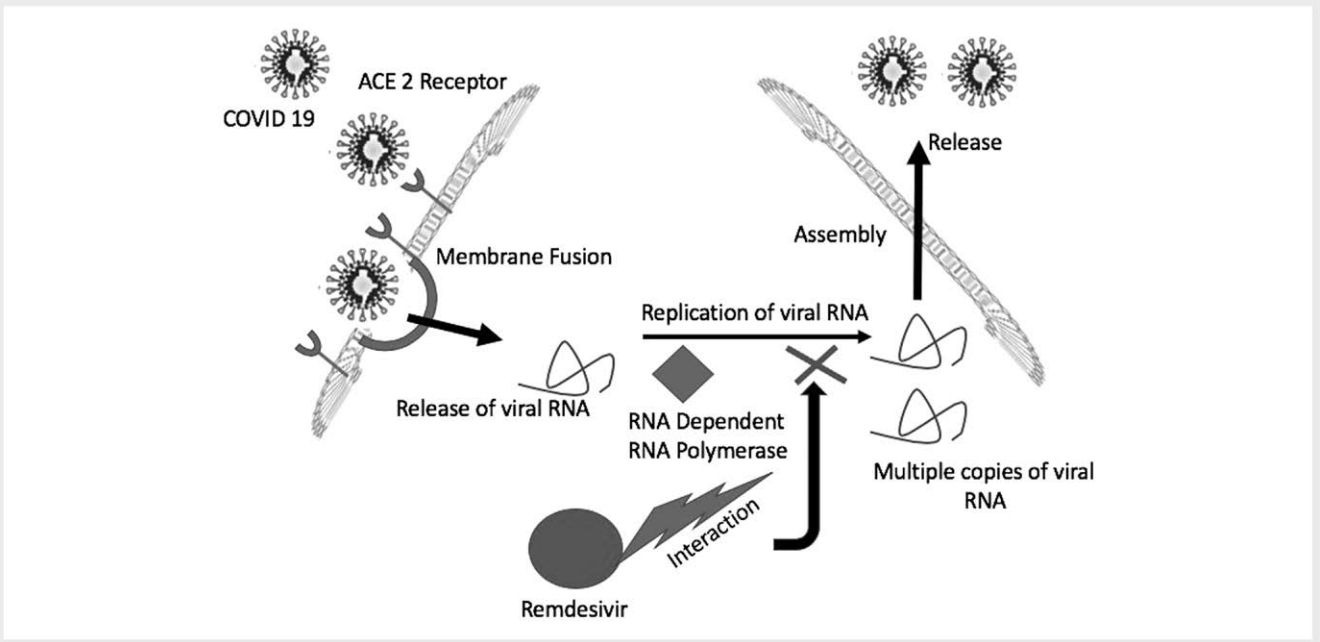
Dosage and use

The USFDA through EUA suggests the use of Remdesivir, administered through intravenous (IV) infusion to treat COVID 19. Though the optimal dose and duration of treatment remains unknown, their suggestion is depicted in ▶ **Table 1** [10].

Other considerations and possible side effect

It is advisable to use Remdesivir during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus. Since the pharmacokinetic analysis of Remdesivir is unavailable for patient with renal as well as hepatic imparement, its use is subject to potential risk and benefit consideration i. e. when the potential benefit outweighs the potential risk. Hepatic laboratory testing is compulsory during treatment [10].

Several infusions related reactions and symptoms including hypotension, nausea, vomiting, diaphoresis etc. are also reported in some case, that might require discontinuing the drug if clinically significant reaction takes place. Alanine aminotransferase (ALT)



▶ **Fig. 2** Plausible mechanism of action of Remdesivir against COVID19.

elevation is also seen [10]. The most common adverse events were increased hepatic enzymes, diarrhea, rash, renal impairment, and hypotension. In general, adverse events were more common in patients receiving invasive ventilation [11].

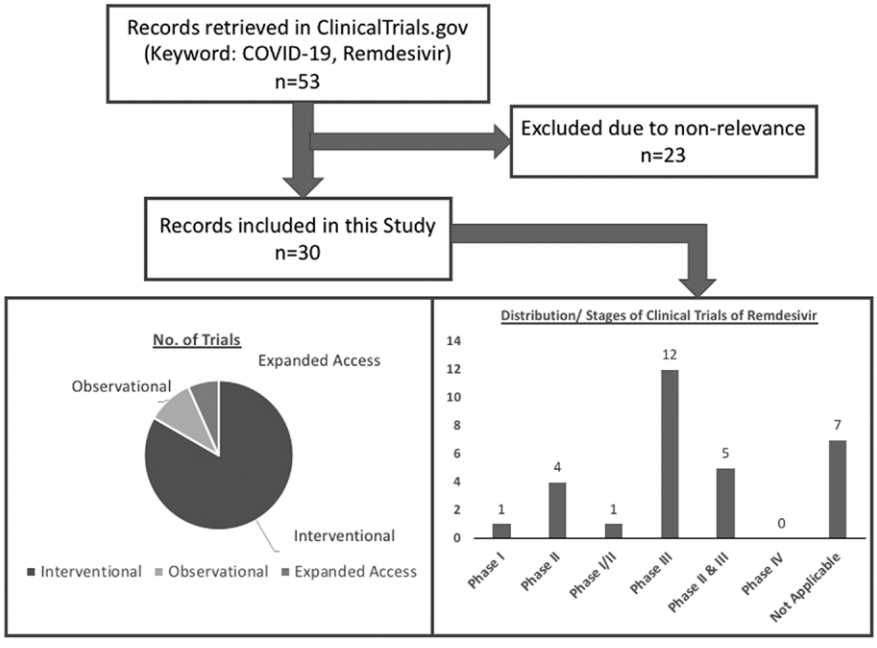
The empirical non-clinical data of side-effect of Remdesivir is limited to mostly in-vitro observations. However, in-vivo pharmacological studies showed that Remdesivir may transiently increase respiratory rate while no significant effect on respiration or EKG have been recorded. Remdesivir is also negative in genotoxicity studies. No renal or hepatic abnormalities were attributed to Remdesivir usage [12]. No effect on CNS and cardiovascular function have been reported [13]. Considering these facts, Remdesivir is still not beyond question [14] and remains incompletely defined in human population [15].

Clinical research output

The process of systemic review was followed (▶ **Figure 3**) to analyze the recent developments of Remdesivir in clinical studies from NIH: US National Library of Medicine [16]. At present (till Sep 2020) 30 clinical studies could be traced involving Remdesivir (Refer ▶ **Table 2**) from the NIH, US National Library of Medicine Clinical Trial Registry (ClinicalTrials.gov) out of which 25 are of interventional type, 3 are observational and rest 2 are Expanded access type. Most of the clinical trials are in stage II and stage III (22 out of 30) indicating promising initial results yet require more time for validation and declared to be safe. Most of the trials are presently in recruiting stage while a mere 1–2 studies have been concluded. Medicinal intervention to treat COVID 19 by the process of drug repurposing as well as novel antiviral candidates could be found from

▶ **Table 1** Dose of Remdsivir suggested by USFDA [7].

Sl No	Target Patient	Condition	Dose	Treatment Duration
1	Adults and pediatric patients weighing ≥40 kg	Requiring invasive mechanical ventilation and/or ECMO	Single loading dose of 200 mg infused intravenously over 30–120 minutes on Day 1 Once-daily maintenance doses of 100 mg infused intravenously over 30–120 minutes for 9 days	10 days
2	Adults and pediatric patients weighing ≥40 kg	Not requiring invasive mechanical ventilation and/or ECMO	Single dose of 200 mg infused intravenously over 30–120 minutes on Day 1 Once-daily maintenance doses of 100 mg infused intravenously over 30–120 minutes for 4 days	5 days (May be extended upto 5 additional days if clinical improvement not demonstrated by patient
3	Pediatric patients with body weight between 3.5 kg and <40 kg	Requiring invasive mechanical ventilation and/or ECMO	Single loading dose of remdesivir 5 mg/kg IV (infused over 30–120 min) on Day 1 Remdesivir 2.5 mg/kg IV (infused over 30–120 min) once daily for 9 days ?	10 days
4	Pediatric patients with body weight between 3.5 kg and <40 kg	Not requiring invasive mechanical ventilation and/or ECMO	Single loading dose of remdesivir 5 mg/kg IV (infused over 30–120 min) on Day 1 Remdesivir 2.5 mg/kg IV (infused over 30–120 min) once daily for 4 days	5 days (May be extended upto 5 additional days if clinical improvement not demonstrated by patient



▶ **Fig. 3** Systemic Review of Clinical Trials of remdesivir.

▶ **Table 2** Details of Clinical Trials on Remdesvir for therapeutic application against virus (especially COVID19).

Sl No	Clinical Trial (Title)	Primary Objectives	Study Type * (I/O/EA)	Status * *	Study Start & Completion Date	Phase	Observation/ Interpretation	Study conducted by	Reference (ClinicalTrials.gov Identifier)
1	Multicenter, Retrospective Study of the Effects of Remdesivir in the Treatment of Severe Covid-19 Infections (REMDECO-19)	This study is a retrospective cohort trial to assess the efficacy of remdesivir in hospitalized adult patients diagnosed with COVID-19	O	R	Start: 05/05/20 Completion: June 2020	NA	Not Available	Assistance Publique - Hôpitaux de Paris	NCT04365725
2	Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of Remdesivir (GS-5734™) in Participants From Birth to < 18 Years of Age With Coronavirus Disease 2019 (COVID-19) (CARAVAN	To evaluate the safety, tolerability, and pharmacokinetics (PK) of remdesivir (RDV) in participants with laboratory-confirmed coronavirus disease 2019 (COVID-19) aged 0 days to < 18 years.	I	R	Start: 21/07/20 Completion: Feb 2021 (Estimated)	II/III	Not Available	Gilead Sciences	NCT04431453
3	A Trial of Remdesivir in Adults With Mild and Moderate COVID-19	Time to Clinical recovery (TTCR)	I	S	Start: 12/02/20 Completion: 15/04/20	III	Not Available	China-Japan Friendship Hospital	NCT04252664
4	Expanded Access Remdesivir (RDV; GS-5734™)	The treatment of communicable Novel Coronavirus (CODIV-19) of 2019 with Remdesivir (RDV; GS-5734™)	EA	A	Start: 10/03/20	NA	Not Available	U.S. Army Medical Research and Development Command	NCT04302766
5	Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants With Severe Coronavirus Disease (COVID-19)	Evaluating Safety of Remdesivir	I	C	Start: 06/03/20 Completion: 09/04/20	III	In patients with severe Covid-19 not requiring mechanical ventilation, this trial did not show a significant difference between a 5-day course and a 10-day course of remdesivir.	Gilead Sciences	NCT04292899
6	Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants With Moderate Coronavirus Disease (COVID-19) Compared to Standard of Care Treatment	To evaluate the efficacy of 2 remdesivir (RDV) regimens compared to standard of care (SOC), with respect to clinical status and to evaluate 5-day and 10-day dosing durations of the investigational antiviral remdesivir in hospitalized patients with severe manifestations of COVID-19 disease	I	C	Start: 15/03/20 Completion: May 2020 (Estimated)	III	The study demonstrated that patients receiving a 10-day treatment course of remdesivir achieved similar improvement in clinical status compared with those taking a 5-day treatment course	Gilead Sciences	NCT04292730

▶ **Table 2** Continued.

Sl No	Clinical Trial (Title)	Primary Objectives	Study Type * (I/O/EA)	Status * *	Study Start & Completion Date	Phase	Observation/ Interpretation	Study conducted by	Reference (ClinicalTrials.gov Identifier)
7	Expanded Access Treatment Protocol: Remdesivir (RDV; GS-5734) for the Treatment of SARS-CoV2 (CoV) Infection (COVID-19)	To provide expanded access of remdesivir (RDV) for the treatment of severe acute respiratory syndrome coronavirus (SARS-CoV2) infection.	EA	A	Start: 27/03/20	NA	Not Available	Gilead Sciences	NCT04323761
8	GS-5734 to Assess the Antiviral Activity, Longer-Term Clearance of Ebola Virus, and Safety in Male Ebola Survivors With Evidence of Ebola Virus Persistence in Semen	This study is a double-blind, randomized, two-phase (treatment and longer-term follow-up), two- arm trial of GS-5734 versus placebo among male Ebola survivors with persistent Ebola virus RNA in their semen. Antiviral activity, as well as safety and tolerability, are assessed during the treatment phase.	I	C	Start: 01/07/16 Completion: 07/10/19	II		National Institute of Allergy and Infectious Diseases (NIAID)	NCT02818582
9	Treatments for COVID-19: Canadian Arm of the SOLIDARITY Trial (CATCO)	To evaluate the clinical efficacy and safety of lopinavir/ritonavir relative to the control arm in participants hospitalized with COVID-19, specifically looking at the subjects clinical status at day 29 as measured on a 10-point ordinal scale through a pro-portional odds model.	I	R	Start: 18/03/20 Completion: Mar 2022 (Estimated)	II	Not Available	Sunnybrook Health Sciences Centre	NCT04330690
10	The Efficacy of Different Anti-viral Drugs in COVID 19 Infected Patients	The (World Health Organization) WHO NOR-(Coronavirus infectious disease) COVID 19 study is a multi-centre, adaptive, randomized, open clinical trial to evaluate the safety and efficacy of hydroxy-chloroquine, remdesivir and standard of care in hospitalized adult patients diagnosed with COVID-19.	I	R	Start: 28/03/20 Completion: Aug 2020 (Estimated)	II & III	Not Available	Oslo University Hospital	NCT04321616

▶ **Table 2** Continued.

Sl No	Clinical Trial (Title)	Primary Objectives	Study Type * (I/O/EA)	Status * *	Study Start & Completion Date	Phase	Observation/ Interpretation	Study conducted by	Reference (ClinicalTrials.gov Identifier)
11	Investigational Therapeutics for the Treatment of People With Ebola Virus Disease	A Multicenter, Multi-Outbreak, Randomized, Controlled Safety and Efficacy Study of Investigational Therapeutics for the Treatment of Patients With Ebola Virus Disease	I	R/C	Start: 21/11/18 Completion: 09/09/19	II & III	Both MAb114 and REGN-EB3 were superior to ZMapp in reducing mortality from EVD [18]	National Institutes of Health Clinical Center (CC) (National Institute of Allergy and Infectious Diseases (NIAID))	NCT03719586
12	Trial of Treatments for COVID-19 in Hospitalized Adults (DisCoVeRy)	This study is a multi-centre, adaptive, randomized, open clinical trial of the safety and efficacy of treatments for COVID-19 in hospitalized adults.	I	R	Start: 22/03/20 Completion: Mar 2023 (Estimated)	III	Not Available	Institut National de la Santé Et de la Recherche Médicale, France	NCT04315948
13	Adverse Events Related to Treatments Used Against Coronavirus Disease 2019 (CovidTox)	This study investigates reports of adverse events related to used molecules, including but not limited to protease inhibitors (lopinavir/ritonavir), chloroquine, azithromycin, remdesivir and interferon beta-1a.	I	R	Start: 17/03/20 Completion: Jan 2021 (Estimated)	NA	Not Available	Groupe Hospitalier Pitie-Salpetriere	NCT04314817
14	Long-term Use of Drugs That Could Prevent the Risk of Serious COVID-19 Infections or Make it Worse (TRAPSAH)	To assess the risk of moderate to serious COVID-19 infections in patients using synthetic anti-malarial drugs (AMD) or anti-hypertensive drugs (Angiotensin receptor-blocking/Angiotensin-converting-enzyme inhibitors).	O	NYR	Start: 22/04/20 Completion: June 2020 (Estimated)	NA	Not Available	Assistance Publique - Hôpitaux de Paris	NCT04356417

▶ **Table 2** Continued.

Sl No	Clinical Trial (Title)	Primary Objectives	Study Type * (I/O/EA)	Status * *	Study Start & Completion Date	Phase	Observation/ Interpretation	Study conducted by	Reference (ClinicalTrials.gov Identifier)
15	Effect of Treatments in Patients Hospitalized for Severe COVID-19 Pneumonia: a Multicenter Cohort Study	Using patients' registries from several hospitals in Paris, the investigators retrospectively analyzed associations between specific treatments, including but not limited to hydroxychloroquine, azithromycin, remdesivir, baricitinib, tocilizumab, sarilumab, lopinavir/ ritonavir and oseltamivir; and clinical outcomes including, death and mechanical ventilation.	O	R	Start: 14/03/20Completion: Dec 2020 (Estimated)	NA	Not Available	Groupe Hospitalier Pitie-Salpetriere	NCT04365764
16	Effectiveness and Safety of Medical Treatment for SARS-CoV-2 (COVID-19) in Colombia	To Evaluate the effectiveness and safety of pharmacological therapies used to treat adult patients with COVID-19.	I	NYR	Start: 11/05/20 Completion: Oct 2020 (Estimated)	II & III	Not Available	Universidad Nacional de Colombia	NCT04359095
17	Study in Participants With Early Stage Coronavirus Disease 2019 (COVID-19) to Evaluate the Safety, Efficacy, and Pharmacokinetics of Remdesivir Administered by Inhalation	To characterize the impact of inhaled remdesivir (RDV) on severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral load in participants with early stage coronavirus disease 2019 (COVID-19)	I	NYR	Start: Sep 2020 Completion: Oct 2020 (Estimated)	I/II	Not Available	Gilead Sciences	NCT04539262
18	Study to Evaluate the Efficacy and Safety of Remdesivir (GS-5734™) Treatment of Coronavirus Disease 2019 (COVID-19) in an Outpatient Setting	To evaluate the efficacy of remdesivir (RDV) in reducing the rate of hospitalization or death in non-hospitalized participants with early stage coronavirus disease 2019 (COVID-19) and to evaluate the safety of RDV administered in an outpatient setting.	I	NYR	Start: Sep 2020 Completion: Dec 2020 (Estimated)	III	Not Available	Gilead Sciences	NCT04501952
19	A Trial of Remdesivir in Adults With Severe COVID-19	To determine the time to clinical improvement	I	T	Start: 06/02/20 Completion: Dec 2020 (Estimated)	III	Not Available	China-Japan Friendship Hospital	NCT04257656

▶ **Table 2** Continued.

Sl No	Clinical Trial (Title)	Primary Objectives	Study Type * (I/O/EA)	Status * *	Study Start & Completion Date	Phase	Observation/ Interpretation	Study conducted by	Reference (ClinicalTrials.gov Identifier)
20	I-SPY COVID-19 TRIAL: An Adaptive Platform Trial for Critically Ill Patients	To rapidly screen promising agents, in the setting of an adaptive platform trial, for treatment of critically ill COVID-19 patients	I	R	Start: 31/07/20 Completion: Jul 2022 (Estimated)	II	Not Available	QuantumLeap Healthcare Collaborative	NCT04488081
21	Investigational Treatments for COVID-19 in Tertiary Care Hospital of Pakistan	To study the role of Investigational Therapies Alone or in Combination to Treat Moderate, Severe and Critical COVID-19	I	C	Start: 01/04/20 Completion: 20/07/20	NA	Not Available	UNICEF	NCT04492501
22	Therapeutics for Inpatients With COVID-19 (TICO)	To study the safety and effectiveness of different drugs in treating COVID-19 in people who have been hospitalized with the infection	I	R	Start: 04/08/20 Completion: Jul 2021 (Estimated)	III	Not Available	National Institute of Allergy and Infectious Diseases (NIAID)	NCT04501978
23	Safety, Tolerability and Pharmacokinetics of Inhaled Nanoparticle Formulation of Remdesivir (GS-5734) and NA-831 (NEUROSIVIR)	To evaluate the safety, tolerability and pharmacokinetics of inhaled nanoparticle nanoparticle formulation of Remdesivir (GS-5734) alone and in combination with NA-831 in 48 healthy volunteers	I	R	Start: 15/09/20 Completion: Dec 2020 (Estimated)	I	Not Available	NeuroActiva, Inc.	NCT04480333
24	Study of Merimepodib in Combination With Remdesivir in Adult Patients With Advanced COVID-19	To assess the safety and efficacy of merimepodib (MMPD) oral solution when administered in combination with remdesivir in adult patients with advanced COVID-19.	I	R	Start: 16/06/20 Completion: Aug 2020 (Estimated)	II	Not Available	ViralClear Pharmaceuticals, Inc.	NCT04410354
25	A Study to Evaluate the Efficacy and Safety of Remdesivir Plus Tocilizumab Compared With Remdesivir Plus Placebo in Hospitalized Participants With Severe COVID-19 Pneumonia (REMDACTA)	To evaluate the efficacy and safety of combination therapy with remdesivir plus tocilizumab compared with remdesivir plus placebo in hospitalized patients with COVID-19 pneumonia.	I	R	Start: 16/06/20 Completion: Dec 2020 (Estimated)	III	Not Available	Hoffmann-La Roche	NCT04409262
26	Remdesivir vs Chloroquine in Covid 19	To compare the efficacy of the drugs: Remdesivir & Chloroquine	I	R	Start: 16/06/20 Completion: Dec 2029 (Estimated)	II/III	Not Available	Tanta University	NCT04345419

▶ **Table 2** Continued.

Sl No	Clinical Trial (Title)	Primary Objectives	Study Type * (I/O/EA)	Status * *	Study Start & Completion Date	Phase	Observation/ Interpretation	Study conducted by	Reference (ClinicalTrials.gov Identifier)
27	Adaptive COVID-19 Treatment Trial 2 (ACTT-2)	ACTT-2 will evaluate the combination of baricitinib and remdesivir compared to remdesivir alone	I	NR	Start: 08/05/20 Completion: Aug 2023 (Estimated)	III	Not Available	National Institute of Allergy and Infectious Diseases (NIAID)	NCT04401579
28	Adaptive COVID-19 Treatment Trial 3 (ACTT-3)	To evaluate the safety and efficacy of novel therapeutic agents in hospitalized adults diagnosed with COVID-19	I	R	Start: 04/08/20 Completion: Nov 2023 (Estimated)	III	Not Available	National Institute of Allergy and Infectious Diseases (NIAID)	NCT04492475
29	Adaptive COVID-19 Treatment Trial (ACTT)	To evaluate the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in Hospitalized Adults	I	C	Start: 21/02/20 Completion: 21/05/20	III	Remdesivir was superior to placebo in shortening the time to recovery in adults hospitalized with Covid-19 and evidence of lower respiratory tract infection [19]		NCT04280705
30	Multi-site Adaptive Trials for COVID-19	to evaluate the clinical efficacy of COVID-19 treatments consisting of standard of care (i. e. Remdesivir), vs SOC with high dose famotidine in patients hospitalized and meeting radiologic criteria for COVID-19 disease	I	R	Start: 07/04/20 Completion: Sep 2020 (Estimated)	III	Not Available	Northwell Health	NCT04370262

* Study Type: I= Interventional, O= Observational, EA: Expanded Access; * * Status: Not Yet Recruiting= NYR, Recruiting= R, Terminated= T, Suspended= S, Available= A, Completed= C.

▶ **Table 3** List of Publications depicting results of clinical trials on Remdesivir (Source: pubmed.gov).

Sl No	Year of Publication	Title of Publication	Significant Observation	Reference
1	2020	Remdesivir in adults with severe COVID-19: a randomised, double-blind, placebo-controlled, multicentre trial	This study of adult patients admitted to hospital for severe COVID-19 showed thatremdesivir was not associated with statistically significant clinical benefits. However, the numerical reduction in time to clinical improvement in those treated earlier requires confirmation in larger studies.	[17]
2	2019	A Randomized, Controlled Trial of Ebola Virus Disease Therapeutics	Although several experimental therapeutics for Ebola virus disease (EVD) have been developed, the safety and efficacy of the most promising therapies were addressed through a randomized, controlled trial. A trial of 681 patients was conducted that showed both MAb114 and REGN-EB3 were superior to ZMapp and Remdesivir in reducing mortality from EVD.	[18]
3	2018	Randomised controlled trial begins for Ebola therapeutics	A trial to assess the efficacy of investigational therapeutics against Ebola virus disease has been launched in DR Congo. The trial is designed to test the safety, efficacy, and feasibility of investigational therapeutics (Remdesivir) against Ebola virus disease	[20]
4	2020	Compassionate remdesivir treatment of severe Covid-19 pneumonia in intensive care unit (ICU) and Non-ICU patients: Clinical outcome and differences in post-treatment hospitalisation status	This prospective (compassionate), open-label study of remdesivir, which was conducted that showed remdesivir can benefit patients with SARS-CoV-2 pneumonia hospitalised outside ICU where clinical outcome was better and adverse events are less frequently observed.	[21]
5		Safety, Tolerability, and Pharmacokinetics of Remdesivir, An Antiviral for Treatment of COVID-19, in Healthy Subjects	Remdesivir exhibited favorable safety and PK profiles that supported once-daily dosing.	[22]
6	2020	Effect of Remdesivir vs. Standard Care on Clinical Status at 11 Days in Patients With Moderate COVID-19: A Randomized Clinical Trial	Randomised control trial was conducted on 596 patients with moderate COVID-19. 10 day course of Remdesivir did not show statistically significant difference in clinical status compared with standard care while patient randomised to 5 day course showed statistically significant difference in clinical status compared with standard care. However the difference was uncertain clinical importance.	[23]
7	2020	Respuestas rápidas a la pandemia de COVID-19 a través de la ciencia y la colaboración global: el ensayo clínico Solidaridad. [Article in Spanish]	In this trial ethical and moral obligation of patients are evaluated in terms of effective treatment. The trial is a reproduction of Remdesivir and other drug usage to identify whether the drugs offer real time benefit to patients.	[24]

Feb 2020, that has peaked up since the declaration of pandemic by WHO on 12th March 2020.

Analyzing the clinical trials from ▶ **Table 2** it is evident that there is attempt to use Remdesivir alone or in combination with other drugs for the treatment of COVID 19. The non-availability of any suitable drug for the therapeutic purpose of COVID 19 as well as lack of information regarding safety issue of Remdesivir has promted its use only in hospital set-up and that too for critically ill patents. Data of adverse drug effect and long term use are expected only by the end of this year through several studies. Only a mere handful of publications are reported from the results of clinical trials (17, 18) while most of them are yet to be completed and still inconclusive. As a result, Remdesivir still remains as investigational drug, distant from USFDA approval.

Scientific Publications

There has been 660 Scientific publications found on the keyword 'Remdesivir; in pubmed.gov. out of which 636 are from the current year. However, a majority of them are review articles and meta-analysis while only 7 reflect results of clinical trials. The following ▶ **Table 3** summarizes the clinical results reflected in research publication.

Conclusion

Remdesivir is presently a 'molecule of hope' to the world to stop the menace of COVID19. However, it has to cross stringent safety regulations and clinical trial to be out of question. It is to be remembered that Remdesivir is still not a USFDA approved drug and its efficacy against COVID 19 are initial result that requires subsequent validation and safety/ risk analysis studies for a longer duration to act as a full proof weapon against COVID 19. Careful monitoring of patient condition and parameters are warranted during Remdesivir administration. Scientific research should also look beyond this molecule to come up with better alternatives, which remains a challenge considering present situation.

Conflict of Interest

The author declares that there is no conflict of interest.

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