

Appendix 4. Registered trials of remdesivir for treatment of covid-19

Registration No./Short name	Study design	Phase	Countries of recruitment	Sample size	Interventions	The status of recruitment	Scientific title of the trial
Randomised controlled trial							
EUCTR2020-000936-23/DisCoVeRy	Open-label, four-arm, randomised controlled trial	Phase 3	France, Austria	3100	Arm 1: Remdesivir (iv) Arm 2: Lopinavir +Ritonavir (po) Arm 3: Rebif (Intravenous use, Subcutaneous use) Arm 4: Hydroxychloroquine (200mg,	Pending	Multi-centre, adaptive, randomised trial of the safety and efficacy of treatments of COVID-19 in hospitalized adults - DisCoVeRy
EUCTR2020-000982-18/NOR-SOLIDARITY and S-ReCOVID 19	Three-arm, randomised controlled trial	Phase 3	Norway, Sweden	1218	Arm 1: Remdesivir (100mg, iv) Arm 2: Hydroxychloroquine sulphate (200mg, po) Arm 3: Standard of care	Pending	The NOR Solidarity multi-center trial on the efficacy of different anti-viral drugs in SARS-CoV-2 infected patients (COVID-19). – NOR-SOLIDARITY/ The NOR-SWE Solidarity multicenter trial on the efficacy of different anti-viral drugs in SARS-CoV-2 infected patients.

EUCTR2020-001366-11/SOLIDARITY	Open-label, five-arm, randomised controlled trial	Phase 4	Spain, Lithuania, Ireland, Italy, Portugal, Romania, Latvia	10000	<p>Arm 1: Remdesivir (100mg, iv)+standard of care</p> <p>Arm 2: Chloroquine (250mg, po)+hydroxychloroquine (200mg, po)+standard of care</p> <p>Arm 3: Ritonavir/Lopinavir (200mg, po) +standard of care</p> <p>Arm 4: Interferon Beta A1 (152g, parenteral use)+standard of care</p> <p>Arm 5: Standard of care</p>	Pending	An international randomised trial of additional treatments for COVID-19 in hospitalised patients who are all receiving the local standard of care - Solidarity
EUCTR2020-001784-88-FI/SOLIDARITY	Open-label, two-arm, randomised controlled trial	Phase 3	Finland	582	<p>Arm 1: Remdesivir (iv)</p> <p>Arm 2: Standard of care</p>	Pending	WHO SOLIDARITY Finland: The multi-center trial on the efficacy of different anti-viral drugs in SARS-CoV-2 infected patients (COVID-19) -
IRCT20200405046953N1/SOLIDARITY	Open-label, five-arm, randomised controlled trial	Phase 3	Iran	3000	<p>Arm 1: Remdesivir (iv, qd, 10 days)+standard of care</p> <p>Arm 2: Chloroquine or Hydroxychloroquine (po, two loading doses, then bid, 10 days)+standard of care</p> <p>Arm 3: Lopinavir with Ritonavir (bid, po, 14 days)+standard of care</p> <p>Arm 4: Lopinavir with Ritonavir (bid, po, 14 days)+Interferon (qd, iv, 6 days)+standard of care</p> <p>Arm 5: Standard of care</p>	Completed	Randomised trial of additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care- Iranian SOLIDARITY multicentre trial

ISRCTN83971151/SOLIDARITY	Open-label, five-arm, randomised controlled trial	Phase 3	Argentina, Brazil, Canada, Germany, Honduras, India, Indonesia, Iran, Ireland, Israel, Italy, Kenya, Lebanon, Malaysia, Norway, Peru, Philippines, Qatar, Saudi Arabia, South Africa, Spain, Switzerland,	at least several thousand patients	<p>Arm 1: Remdesivir (iv, qd, 10 days) +standard of care</p> <p>Arm 2: Chloroquine (po, two loading doses, then bid, 10 days) or hydroxychloroquine (po, two loading doses, then bid, 10 days) +standard of care</p> <p>Arm 3: Lopinavir (po, bid, 14 days)+ritonavir (po, bid, 14 days)+standard of care</p> <p>Arm 4: Lopinavir (po, bid, 14 days)+ritonavir (po, bid, 14 days)+Interferon (iv, qd, 6 days)+standard of care</p> <p>Arm 5: Standard of care</p>	Recruiting	An international randomised trial of additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care
JPRN-jRCT2031190264/ACTT	Double-blind, two-arm, randomised controlled trial	Phase 3	USA, Korea, Japan	100	<p>Arm 1: Remdesivir (200mg, qd, iv, 1 day followed by 100mg, qd, iv, 9 days or until discharge from hospital)</p> <p>Arm 2: Placebo (200mg, qd, iv, 1 day followed by 100mg, qd, iv, 9 days or until discharge from hospital)</p>	Not yet started	A Multicenter, Adaptive, Randomised Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in Hospitalized Adults - Adaptive

LBCTR202004 3495/SOLIDAR ITY	Open-label, five- arm, randomised controlled trial	Phase 3	Lebanon	1000	<p>Arm 1: Remdesivir (iv, qd, 10 days)+Standard of care</p> <p>Arm 2: Chloroquine or hydroxychloroquine (po, two loading doses, then bid, 10 days)+Standard of care</p> <p>Arm 3: Lopinavir + Ritonavir (bid, po, 14 days)+Standard of care</p> <p>Arm 4: Lopinavir + Ritonavir (bid, po, 14 days) + Interferon (bid, po, 14 days)+Standard of care</p> <p>Arm 5: Standard of care</p>	Pending	An international randomised trial of additional treatments for COVID-19 in hospitalised patients who are all receiving the local standard of care - SOLIDARITY
NCT04252664	Double-blind, two- arm, randomised controlled trial	Phase 3	China	308	<p>Arm 1: Remdesivir (200mg, 1 day followed by 100mg, qd, iv, 9 days)</p> <p>Arm 2: Placebo (200mg, 1 day followed by 100mg, qd, iv, 9 days)</p>	Suspended	A Phase 3 Randomised, Double-blind, Placebo-controlled Multicenter Study to Evaluate the Efficacy and Safety of Remdesivir in Hospitalized Adult Patients With Mild and Moderate COVID-19.
NCT04257656	Double-blind, two- arm, randomised controlled trial	Phase 3	China	237	<p>Arm 1: Remdesivir (200mg, 1 day followed by 100mg, qd, iv, 9 days)</p> <p>Arm 2: Placebo (200mg, 1 day followed by 100mg, qd, iv, 9 days)</p>	Terminated	A Phase 3 Randomised, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy and Safety of Remdesivir in Hospitalized Adult Patients With Severe COVID-19.

NCT04280705 /ACTT	Double-blind, two-arm, randomised controlled trial	Phase 3	United States, Korea, Denmark, Germany, Greece, Japan, Mexico, Singapore, Spain, United Kingdom	800	<p>Arm 1: Remdesivir (200mg, 1 day followed by 100mg, qd, iv, 9 days or until discharge from hospital)</p> <p>Arm 2: Placebo (200mg, 1 day followed by 100mg, qd, iv, 9 days or until discharge from hospital)</p>	Recruiting	A Multicenter, Adaptive, Randomised Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in Hospitalized Adults
NCT04292730	Open-label, three-arm, randomised controlled trial	Phase 3	United States, Korea, China, France, Germany, Hong Kong, Italy, Japan, Netherlands, Singapore, Spain, Sweden, Switzerland, Taiwan, United Kingdom	1600	<p>Arm 1: Remdesivir (200mg, 1 day followed by 100mg, 4 days)+Standard of care</p> <p>Arm 2: Remdesivir (200mg, 1 day followed by 100mg, 9 days)+Standard of care</p> <p>Arm 3: Standard of care (Continued SOC Therapy)</p> <p>Arm 4: Extension Treatment (Remdesivir 5 or 10 days, Remdesivir 200mg, 1 day followed by 100mg, 9 days)+Standard of care</p>	Not yet started	A Phase 3 Randomised Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants With Moderate COVID-19 Compared to Standard of Care Treatment

NCT04292899	Open-label, four-arm, randomised controlled trial	Phase 3	United States, Korea	6000	<p>Arm 1: Remdesivir (200mg, iv, 1 day followed by 100mg, iv, 4 days), not mechanically ventilated+Standard of care</p> <p>Arm 2: Remdesivir (200mg, iv, 1 day followed by 100mg, iv, 9 days), not mechanically ventilated + Standard of care</p> <p>Arm 3: Remdesivir (200mg, iv, 1 day followed by 100mg, iv, 9 days), mechanically ventilated + Standard of care</p> <p>Arm 4: Remdesivir, 5 or 10 Days (Extension) (200mg, iv, 1 day followed by 100mg, iv, 9 days) , 5 or 10 Days (Extension)+Standard of care</p>	Not yet started	A Phase 3 Randomised Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants With Severe COVID-19
-------------	---	---------	----------------------	------	---	-----------------	--

<p>NCT04315948 /DisCoVeRy</p>	<p>Open-label, five-arm, randomised controlled trial</p>	<p>Phase 3</p>	<p>France, Luxembourg</p>	<p>3100</p>	<p>Arm 1: Remdesivir (200mg, qd, iv, 1 day followed by 100mg, qd, iv, 10 days)+ Standard of care Arm 2: Lopinavir/ritonavir (400 lopinavir mg/100 mg ritonavir, bid, po, 14 days, or 400 lopinavir mg/100 mg ritonavir as a 5-ml suspension, bid, nasogastric tube, 14 days) + Standard of care Arm 3: Lopinavir/ritonavir (400 lopinavir mg/100 mg ritonavir, bid, po, 14 days, or 400 lopinavir mg/100 mg ritonavir as a 5-ml suspension, bid, nasogastric tube, 14 days) +Interferon β1a (44 μg, iH, a total of 3 doses in 6 days (day 1, day 3, day 6))+ Standard of care Arm 4: Hydroxychloroquine (400mg, bid, po 1 day followed by 400mg, qd, po, 9 days, or 600mg, bid, nasogastric tube, 1 day followed by 400mg, qd, nasogastric tube, 9 days)+ Standard of care Arm 5: Standard of care</p>	<p>Recruiting</p>	<p>Multi-centre, Adaptive, Randomised Trial of the Safety and Efficacy of Treatments of COVID-19 in Hospitalized Adults</p>
-----------------------------------	--	----------------	-------------------------------	-------------	--	-------------------	---

NCT04321616	Open-label, three-arm, randomised controlled trial	Phase 2 /Phase 3	Norway	700	<p>Arm 1: Remdesivir (200mg followed by 100mg, qd, iv, 10 days)</p> <p>Arm 2: Hydroxychloroquine (800mg followed by 400mg, bid, po, 10 days)</p> <p>Arm 3: Standard of care</p>	Recruiting	The (Norwegian) NOR Solidarity Multicenter Trial on the Efficacy of Different Anti-viral Drugs in SARS-CoV-2 Infected Patients
NCT04330690 /CATCO	Open-label, four-arm, randomised controlled trial	Phase 2	Canada	2900	<p>Arm 1: Remdesivir (200mg, qd, iv, 1 day followed by 100mg, qd, iv, 9 days) + standard of care</p> <p>Arm 2: lopinavir/ritonavir (400mg/100mg, po, 14 days or until discharge from hospital) + standard of care</p> <p>Arm 3: Hydroxychloroquine (800mg, bid, po, 1 day followed by 400mg, bid, po, 10 days) + standard of care</p> <p>Arm 4: Standard of care</p>	Recruiting	A Multi-centre, Adaptive, Randomised, Open-label, Controlled Clinical Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in Hospitalized Patients (CATCO: Canadian Treatments for COVID-19), in Conjunction With the Public Health Emergency SOLIDARITY Trial (World Health Organization)

NCT04349410 /FMTVDM	Single-blind, eleven-arm, randomised controlled trial	Phase 2 /Phase 3	United States	500	<p>Arm 1: Remdesivir (200mg, iv, on day 1 followed by 100mg, iv, qd, 10 days)</p> <p>Arm 2: Hydroxychloroquine (200mg, po, tid, 10 days) + Azithromycin (500mg, iv, 1 day followed by 250mg, iv, 4days)</p> <p>Arm 3: Hydroxychloroquine (200mg, po, tid, 10 days) + Doxycycline (100mg, iv, bid, with each dose given over 1 to 4-hours)</p> <p>Arm 4: Hydroxychloroquine (200mg, po, tid, 10 days) +Clindamycin (150-450mg, po, qid, 10 days OR 4800 mg, iv, qd - beginning with 150mg initial rapid infusion, followed by continuous infusion, 7 days)</p> <p>Arm 5: Hydroxychloroquine (200mg, po, tid, 10 days) +Primaquine (200mg, po, on Day 1)+Clindamycin 150-450mg, po, qid, 10days OR 4800mg, iv, qd - beginning with 150mg initial rapid infusion, followed by continuous infusion, 7 days)</p> <p>Arm 6: Hydroxychloroquine (Day 1: 800mg, po followed by 400mg 8 hours later. Days 2 and 3: 400mg, po, qd)+Primaquine (200mg, po, on Day 1)+Clindamycin (150-450mg, po, qid, 10 days OR 4800mg, iv, qd - beginning with 150 mg initial rapid infusion, followed by continuous infusion)</p>	Recruiting	The Fleming [FMTVDM] Directed CoVid-19 Treatment Protocol
---------------------	---	------------------	---------------	-----	---	------------	---

NCT04401579 /ACTT-II	Double-blind, two-arm, randomised controlled trial	Phase 3	United States, Japan, Korea, Mexico, Singapore	1032	Arm 1: Remdesivir (200mg, qd, iv, 1 day followed by 100mg, qd, iv, 9 days) + baricitinib (4mg, qd, po, 14 days) Arm 2: Remdesivir (200mg, qd, iv, 1 day followed by 100mg, qd, iv, 9 days) + baricitinib placebo (qd, po, 14 days)	Recruiting	A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in Hospitalized Adults (ACTT-II)
NCT04409262 /REMDACTA	Double-blind, two-arm, randomised controlled trial	Phase 3	United States, Brazil	450	Arm 1: Remdesivir (iv, loading dose, then qd, iv, 9 days) + tocilizumab (iv, single infusion on Day 1) Arm 2: Remdesivir (iv, loading dose, then qd, iv, 9 days) + placebo (iv, single infusion on Day 1)	Recruiting	A Phase III, Randomized, Double-Blind, Multicenter Study to Evaluate the Efficacy and Safety of Remdesivir Plus Tocilizumab Compared With Remdesivir Plus Placebo in Hospitalized Patients With Severe COVID-19 Pneumonia
NCT04410354	Double-blind, two-arm, randomised controlled trial	Phase 2	United States	40	Arm 1: Remdesivir (200mg, qd, iv, 1 day followed by 100mg, qd, iv, 4 days, may be extended up to a total of 10 days) + merimepodib (400mg – total 1200mg/day, tid, po, 10 days) Arm 2: Remdesivir (200mg, qd, iv, 1 day followed by 100mg, qd, iv, 4 days, may be extended up to a total of 10 days) + placebo (tid, po, 10 days)	Recruiting	A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of Oral Merimepodib in Combination With Intravenous Remdesivir in Adult Patients With Advanced Coronavirus Disease 2019 (COVID-19)

Non-randomised trial (interventional)							
NCT04302766	One-arm, non-randomised trial (interventional)	Phase 1	NR	NR	Remdesivir (regimen not reported)	Not yet started	Intermediate-Size Patient Population Expanded Access Treatment Protocol for Coronavirus Disease 2019 (COVID-19) Remdesivir (RDV, GS-5734™)
NCT04431453 /CARAVAN	One-arm, non-randomised trial (interventional)	Phase 2/ Phase 3	NR	52	Arm 1: Remdesivir (200mg, qd, iv, 1 day followed by 100mg, qd, iv, 9 days) or remdesivir (5mg/kg, qd, iv, 1 day followed by 2.5 mg/kg, qd, iv, 9 days) or remdesivir (dose determined by data from previous cohort)	Not yet started	A Phase 2/3 Single-Arm, Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of Remdesivir (GS-5734™) in Participants From Birth to < 18 Years of Age With COVID-19
Cohort-study							
NCT04365725 /REMDECO-19	One-arm, cohort-study	Unknown	France	200	Remdesivir (regimen not reported)	Recruiting	Multicenter, Retrospective Study of the Effects of Remdesivir in the Treatment of Severe Covid-19

NCT04323761	One-arm, non-randomised trial (interventional)	NR	United States, Australia, Belgium, Canada, Cyprus, Czechia, Estonia, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Switzerland, United Kingdom, Australia,	NR	Remdesivir (iv, over 30 to 120 minutes), unclear how often its administered	Not yet started	Expanded Access Treatment Protocol: Remdesivir (RDV, GS-5734) for the Treatment of SARS-CoV2 (CoV) Infection
-------------	--	----	---	----	---	-----------------	--

IRCT20171122 037571N2	Open-label, one- arm, non- randomised trial (interventional)	Phase 2 /Phase 3	Iran	120	Remdesivir 5 days (for patients over 40 kg or more: 200mg, qd, iv, over 30 minutes, 1 day followed by 100mg, qd, iv, over 30 minutes, 4 days, for patients weighing less than 40 kg: 5 mg/kg, iv, over 30 minutes, 1 day followed by 2.5 mg/kg, qd, iv, over 30 minutes, 4 days) + standard treatment (500mg chloroquine phosphate / 400mg hydroxychloroquine sulfate, single-dose and lopinavir/ritonavir 400/100mg, bid, 5 days or alternatively, atazanavir OR 500mg	Completed	A single-arm multicenter clinical trial to evaluate the safety and efficacy of Remdesivir in COVID-19 patients with progressive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
--------------------------	---	---------------------	------	-----	---	-----------	--

Note: NR: not reported