NIHR | Research Delivery Network

Agile CST 9b

A Multicentre, Adaptive Phase II Randomised Double-Blind Placebo Controlled Trial to Evaluate the Safety, Efficacy and Virological response of ALG-097558 for the Treatment of COVID-19 disease.

CPMS ID (NIHR Portfolio No.)	71585	**IRAS No.**	282781
Sponsor	University of Liverpool		
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Study Information

Expected Study Start Date	Expected Study End Date	Study Follow Up Period (months)
May 2026	March 2027	Up to Day 29.

Study Design & Objectives

This trial is a Multicentre, Adaptive Phase II Randomised Double-Blind Placebo Controlled Trial to Evaluate the Safety, Efficacy and Virological response of ALG-097558 for the Treatment of COVID-19 disease**.**

Safety Objective: Determine the safety and tolerability of ALG-097558.
Efficacy Objective: The primary objective is to determine change in viral titre overtime following administration of ALG-097558 versus placebo

Eligibility

Inclusion Criteria	1. Adults (>/= 18 years of age) with a positive SARS-CoV-2 lateral flow test on screening or Day 1, who are NOT at high risk (as defined in UK DHSC criteria) of progressing to severe COVID-19 disease, within 5 days of symptom onset, with at least one symptom of COVID-19 infection present on the day of randomization and with mild- moderate disease severity at enrolment. 2. Ability to provide informed consent signed by trial participant and are willing and able to comply with all trial procedures and attending clinic visits 3. Women of childbearing potential (WOCBP) and male participants who are sexually active with WOCBP must agree to use two effective methos of contraception, one of which must be highly effective for the duration of the treatment and for 90 Days following the last dose.
Exclusion Criteria	1. Prior SARS-CoV-2 infection diagnosed <90 days before enrolment and/or received any COVID-19 vaccine dose <90 days before enrolment 2. 3 times the upper limit of normal (ULN) or Active Liver disease 3. History or current evidence of cirrhosis 4. Receiving dialysis or have known severe renal impairment defined as CKD stage 5 (an eGFR <15mL/min/1.73 m2 at screening, or current acute kidney injury in most recent eGFR in past 6 months. 5. Pregnant or breast feeding 6. Anticipated transfer to another hospital which is not a trial site within 72 hours

	7. Known allergy to any trial medication 8. Swallowing difficulties 9. Currently receiving ALG-097558, Paxlovid, molnupiravir or remdesivir or any standard of care antiviral therapy for COVID-19 at the time of screening 10. Received sotrovimab at any point during the current SARS-CoV-2 infection prior to enrolment 11. Oxygen saturations <94% on room air. NOTE: Participants on stable oxygen therapy, including use of NIPPV (non-invasive positive pressure ventilation), for a pre-existing medical condition (e.g., COPD) may HRA Protocol Template for CTIMPs Version 1.2 March 2016 AGILE CST9b: ALG097558 Monotherapy Versus Placebo Protocol Version 1.0. 17th December 2025 IRAS ID: 282781 EudraCT: 2020-001860-27 Page 31 of 47 Docusign Envelope ID: 78B18A54-5D03-4AFD-81AA-54F73396B617 be included with oxygen saturation of <94% on room air, provided there is no new increased oxygen requirement. 12. Urgent or expected need for nasal high-flow oxygen therapy or positive pressure ventilation, invasive mechanical ventilation or ECMO. 13. Participants who have taken or require treatment with a comedication that is a strong CYP450 3A4 inhibitor (atazanavir, clarithromycin, itraconazole, posaconazole, voriconazole, nefazodone, nelfinavir, grapefruit juice, HIV protease inhibitors), strong CYP450 3A4 inducers (rifampin, phenytoin, carbamazepine, St. John's Wort) or sensitive substrates of CYP450 2C8 and 2B6 (repaglinide, rosiglitazone, paclitaxel, bupropion) within at least 2 weeks or 5 half-lives (whichever is longer) before the planned first dose of study drug. 14. Participating in another CTIMP trial within 5 half-lives of the last administered dose of an investigational medicinal product. 15. Participants eligible for other antiviral treatment according to DHSC criteria, or those otherwise eligible for CST9a.

Activities

Practice activities	• Database search • Eligibility checks • GP texts/letters • Displaying posters and flyers • Patient referrals
Patient activities	The study will include: • 2 clinic visits: Screening/Day 1 and Day 6 (+/-2 days) at the CRF, • 10 Telephone calls: Day 2, 3, 4, 5, 7, 8, 9, 10, 11 and 29. Participants randomised will receive £900, or £1200 if they to take part in the PK sub-study (an additional PK sample is taken on Day 1, and one is taken at home on Day 3).

Specific Information

Target recruitment per practice	Up to 8 patients
Will recruitment be allocated to practice	No
Recruitment accrual per practice or per patient	Per Patient - £50 per patient randomised Per Practice - £270 set up fee
GCP requirements (Is GCP certification required to conduct this study)	No

Is this study on the PI Associate Scheme?	No
Can the Agile Research Delivery Team support the study?	No
Study Type	PIC study (interventional)

Reimbursement and Invoicing

Service Support Costs (SSCs)	N/A	**Note: Service support costs are paid by the Regional Research Delivery Network North West (RRDN NW) on a quarterly basis. Costs are triggered by providing data of study activities that have commenced (green light date) to the RRDN.** **Service support cost remittance sheets will come from Manchester Foundation Trust Finance Accounts Team**
Research Costs	Per Patient - £50 per patient randomised Per Practice - £270 set up fee	**Note: Research costs will be paid to practices from the study team. You will need to submit an invoice directly to the study team in order for payment to be processed. The contract will list the amount and frequency that you need to invoice for.**
Excess Treatment Costs (ETCs)	N/A	**Note: If excess treatment costs are available, these costs will be paid to you via the RRDN NW and you will be contacted to advise.**