
Full Title: PROphylaxis for paTiEnts at risk of COVID-19 infecTion in Vulnerable population

Short Title: PROTECT – V

EudraCT Number: 2020-004144-28

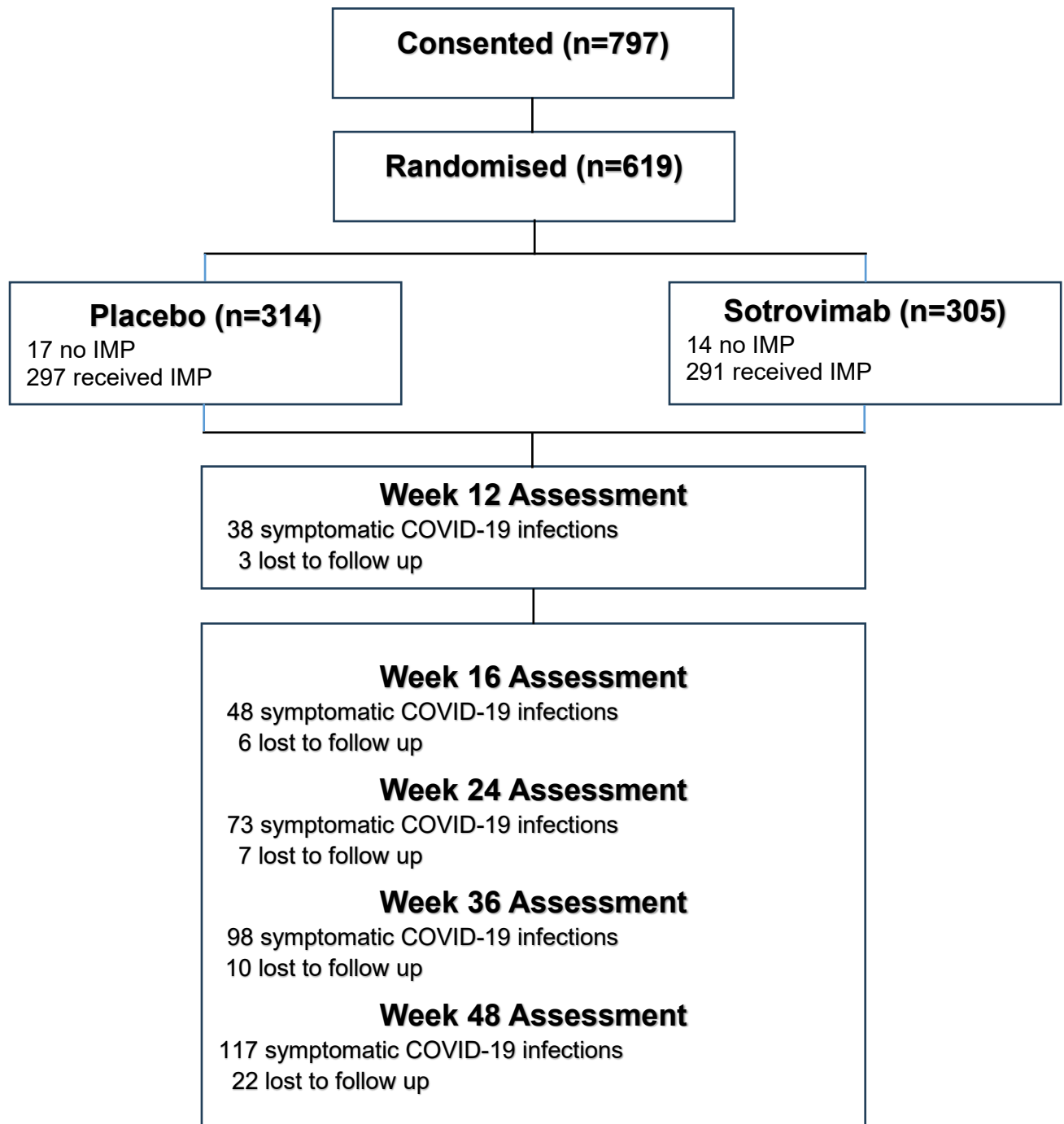
Trial Sponsor: Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge

Trial Funder: LifeArc, KRUK, ACT, GlaxoSmithKline

Sotrovimab arm basic result summary

- Participant flow
- Baseline characteristics
- Primary outcome measure
- Adverse events

Participant flow



Baseline characteristics for participants received IMP

Baseline	Placebo		Sotrovimab		Total	
	N	%	N	%	N	%
Total	297	100.00	291	100.00	588	100.00
Age at consent						
Age<=60	116	39.06	121	41.58	237	40.31
Age>60	181	60.94	170	58.42	351	59.69
Gender						
Female	141	47.47	156	53.61	297	50.51
Male	156	52.53	135	46.39	291	49.49
Disease sub-group						
Dialysis	25	8.42	24	8.25	49	8.33
Autoimmune disease	130	43.77	126	43.30	256	43.54
Transplant	59	19.87	57	19.59	116	19.73
Haematology/oncology	46	15.49	50	17.18	96	16.33
Immunodeficiency	37	12.46	34	11.68	71	12.07
Ethnicity						
White	279	93.94	279	95.88	558	94.90
Black/African/Caribbean/Black British	5	1.68	1	0.34	6	1.02
Asian/Asian British	9	3.03	9	3.09	18	3.06
Other	2	0.67	1	0.34	3	0.51
Multiple or mixed ethnic groups	2	0.67	1	0.34	3	0.51

Primary outcome measure

At week 12, 21 symptomatic COVID-19 infections were observed in the placebo group and 17 in the sotrovimab group with a risk ratio of 0.82 (95% CI 0.43–1.54), $p=0.54$, adjusting for age and disease sub-group. 4/38 (10.5%) patients were hospitalised (3 placebo, 1 sotrovimab). In view of the 250-fold reduction in EC50 with sotrovimab on pseudovirus testing for JN.1, a pre-specified efficacy analysis according to exposure period was performed.

Number and severity of COVID-19 infections at week 12 (primary efficacy endpoint)

Symptomatic COVID-19 infection events	Placebo (N=297)		Sotrovimab (N=291)		Total	
	N	%	N	%	N	%
Symptomatic COVID-19 infection events	21	7.07	17	5.84	38	6.46
COVID-19 infection severity by adapted World Health Organisation (WHO) scale						
Very mild symptoms, no limitations	4		7		11	
Mild, limitations on activities	14		8		22	
Mild, hospitalised, no oxygen requirement	1		1		2	
Moderate, hospitalised, oxygen via mask or	1		0		1	
Death	1		0		1	
Not available	0		1		1	
Symptomatic COVID-19 infection events by JN.1 exposure according to the UK Healthy Security Agency (UKHSA) data						
Before 20 June 2023 (no JN.1 cases reported before 19 June 2023)	9		4		13	
Before 1 November 2023 (>5% JN.1 cases)*	13		8		21	
Before 15 December 2023 (>50% JN.1 cases)	16		10		26	
After 15 December 2023 (JN.1 predominant)#	5		7		12	

*cumulative cases of COVID-19 infection, so includes cases reported in row(s) above.

cases reported before and after 15 December 2023 equate to the total number of symptomatic COVID-19 infections at week 12.

Adverse Events

	Placebo (N=297)		Sotrovimab (N=291)	
	N	%	N	%
Symptoms reported within 24 hours following infusion				
Itching / pruritus	6	2.0	11	3.8
Rash / redness / erythema	4	1.4	3	1.0
Fever	2	0.7	6	2.1
Dyspnoea / wheeze	6	2.0	6	2.1
Rigors/chills	7	2.4	10	3.4
Dizziness	10	3.4	15	5.2
Other (details with over 10 patients listed)	49	16.6	42	14.4
Headache	17	5.7	14	4.8
Fatigue	8	2.7	12	4.1
Nausea	6	2.0	4	1.4
Any above symptoms reported	64	21.6	65	22.3
Symptoms reported within 12 weeks following infusion				
Rash / pruritus	29	9.8	39	13.5
Dyspnoea / wheeze	36	12.2	37	12.8
Serious Adverse Events reported from starting IMP				
Causality – related	0		0	
Causality - unrelated	108		86	

	Placebo (N=297)	Sotrovimab (N=291)
	N	N
AE related to IMP (reported up to day 29)		
10015919 Eye disorders	1	0
10017947 Gastrointestinal disorders	9	5
10018065 General disorders and administration site conditions	6	8
10028395 Musculoskeletal and connective tissue disorders	1	4
10029205 Nervous system disorders	13	11
10037175 Psychiatric disorders	1	1
10038359 Renal and urinary disorders	0	2
10038738 Respiratory, thoracic and mediastinal disorders	1	3
10040785 Skin and subcutaneous tissue disorders	3	2
10043521 Throat irritation	1	0
10047065 Vascular disorders	0	1