



Clinical trial results:

Use of inhaled corticosteroids as treatment of early COVID-19 infection to prevent clinical deterioration and hospitalisation

Summary

EudraCT number	2020-001889-10
Trial protocol	GB
Global end of trial date	04 December 2020

Results information

Result version number	v1 (current)
This version publication date	11 October 2022
First version publication date	11 October 2022

Trial information

Trial identification

Sponsor protocol code	STOIC
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04416399
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Oxford
Sponsor organisation address	Boundary Brook House, Churchill Drive, Oxford, United Kingdom, OX3 7GB
Public contact	Magda Laskawiec-Szkonter, Oxford Respiratory Trials Unit, 44 01865227612, magda.laskawiec@ouh.nhs.uk
Scientific contact	Magda Laskawiec-Szkonter, Oxford Respiratory Trials Unit, 44 01865227612, magda.laskawiec@ouh.nhs.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 December 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 December 2020
Global end of trial reached?	Yes
Global end of trial date	04 December 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Evaluate the effect of inhaled corticosteroid (ICS) therapy compared to standard care in participants with early CoVID-19 illness in reducing COVID related emergency department presentations and/or hospital admissions.

Protection of trial subjects:

Informed consent taken
no invasive techniques conducted

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 146
Worldwide total number of subjects	146
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	136
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruited from start date of study from the community, within 7 days of symptom onset of COVID-19.
Recruited from Oxfordshire UK

Pre-assignment

Screening details:

Had to be within 7 days of symptoms of COVID-19. 167 participants screened. 146 randomised

Period 1

Period 1 title	Study intervention (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
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Arm title	Budesonide
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Arm description:

Study drug arm

Arm type	Experimental
Investigational medicinal product name	Budesonide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder
Routes of administration	Inhalation use

Dosage and administration details:

800mcg 2puffs twice a day

Arm title	usual care
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Arm description:

standard care

Arm type	No intervention
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No investigational medicinal product assigned in this arm

Number of subjects in period 1	Budesonide	usual care
Started	73	73
Completed	73	73

Baseline characteristics

Reporting groups

Reporting group title	Budesonide
Reporting group description:	
Study drug arm	
Reporting group title	usual care
Reporting group description:	
standard care	

Reporting group values	Budesonide	usual care	Total
Number of subjects	73	73	146
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
arithmetic mean	44	45	
full range (min-max)	19 to 71	19 to 79	-
Gender categorical			
Units: Subjects			
Female	41	43	84
Male	32	30	62

Subject analysis sets

Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Intention to treat	

Reporting group values	ITT		
Number of subjects	146		
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			

Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years arithmetic mean full range (min-max)	45 19 to 79		
Gender categorical Units: Subjects			
Female Male	84 62		

End points

End points reporting groups

Reporting group title	Budesonide
Reporting group description:	
Study drug arm	
Reporting group title	usual care
Reporting group description:	
standard care	
Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Intention to treat	

Primary: Treatment failure

End point title	Treatment failure
End point description:	
End point type	Primary
End point timeframe:	
Day 1 to day 28	

End point values	Budesonide	usual care	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	73	73	146	
Units: Number needing urgent treatment	2	11	13	

Statistical analyses

Statistical analysis title	Primary outcome
Comparison groups	Budesonide v usual care
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	0.123
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.033
upper limit	0.213

<div>Variability estimate</div>	<div>Standard error of the mean</div>
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Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 to day 28

Assessment type	Systematic
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Dictionary used

Dictionary name	SNOMED CT
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Dictionary version	CTV3
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Reporting groups

Reporting group title	Budesonide
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Reporting group description: -

Reporting group title	Usual care
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Reporting group description: -

Serious adverse events	Budesonide	Usual care	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 73 (0.00%)	1 / 73 (1.37%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Respiratory, thoracic and mediastinal disorders			
Severe respiratory failure			
subjects affected / exposed	0 / 73 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Budesonide	Usual care	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 73 (6.85%)	0 / 73 (0.00%)	
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 73 (1.37%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			

Sore throat subjects affected / exposed occurrences (all)	4 / 73 (5.48%) 4	0 / 73 (0.00%) 0	
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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/33844996>