Clinical trial results:
A single arm, open-label clinical trial of azithromycin in pulmonary sarcoidosis

Summary

EudraCT number	2019-000580-24
Trial protocol	GB
Global end of trial date	09 September 2020

Results information

Result version number	v1 (current)
This version publication date	12 June 2022
First version publication date	12 June 2022
Summary attachment (see zip file)	Study summary (Azithromycin.pdf)

Trial information

Trial identification

Sponsor protocol code	R2347

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Hull University Teaching Hospitals NHS Trust
Sponsor organisation address	Castle Hill Hospital, Castle Road, Cottingham, Kingston-upon-Hull, United Kingdom, HU16 5JQ
Public contact	Dr Simon Hart, Hull York Medical School/ University of Hull, +44 01482624067, s.hart@hull.ac.uk
Scientific contact	Dr Simon Hart, Hull York Medical School/ University of Hull, +44 01482624067, s.hart@hull.ac.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	09 September 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 September 2020
Global end of trial reached?	Yes
Global end of trial date	09 September 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Assess the effect of azithromycin on cough measured using automated cough counting

Protection of trial subjects:

The investigator or designee will question subjects about AEs and intercurrent illnesses at Baseline and at all subsequent visits since their last visit. The pertinent information will be recorded on the CRF.
Safety will be assessed through monitoring of adverse events/serious adverse events of special interest, physical examinations, vital signs, and 12-lead ECGs. Safety assessment frequency is shown in the Schedule of Assessments and Procedures
Robust consent process in place.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2019
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: 21
Worldwide total number of subjects	21
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)	18
From 65 to 84 years	3

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Once informed consent has been obtained, the following assessments will be performed and recorded:
• Medical history and demographics
• Vital signs (sitting systolic and diastolic blood pressure, pulse, respiration rate, body temperature)
• Weight and height
• Physical examination
• ECG (12 lead)Concomitant medication
• Cough VAS
• LCQ
•

Period 1

Period 1 title	Visit 1
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Test

Arm description:

The Screening/baseline visit will ensure that each subject meets all the specified inclusion criteria and none of the exclusion criteria. Once consented, the Hull Automated Cough Counter will be given to the patient with verbal and written instructions. The initial supply of study drug (azithromycin 250mg once daily) will be issued, with written instructions to take the first dose on the day after completing the cough counting. The subject will return the cough counter for analysis at their convenience.

Arm type	Experimental
Investigational medicinal product name	Azithromycin 250mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Commercially available 250 mg azithromycin, administered as a tablet
oral azithromycin 250 mg once daily for 3 months

Number of subjects in period 1	Test
Started	21
Completed	21

Period 2

Period 2 title	Visit 2
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Test

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Azithromycin 250mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Commercially available 250 mg azithromycin, administered as a tablet
oral azithromycin 250 mg once daily for 3 months

Number of subjects in period 2[1]	Test
Started	20
Completed	20

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: 1 participant left the trial due at 1 month due to work commitments.

Period 3

Period 3 title	Visit 3
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Test

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Azithromycin 250mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Commercially available 250 mg azithromycin, administered as a tablet oral azithromycin 250 mg once daily for 3 months

Number of subjects in period 3	Test
Started	20
Completed	20

Baseline characteristics

End points

End points reporting groups

Reporting group title	Test

Reporting group description:

The Screening/baseline visit will ensure that each subject meets all the specified inclusion criteria and none of the exclusion criteria. Once consented, the Hull Automated Cough Counter will be given to the patient with verbal and written instructions. The initial supply of study drug (azithromycin 250mg once daily) will be issued, with written instructions to take the first dose on the day after completing the cough counting. The subject will return the cough counter for analysis at their convenience.

Reporting group title	Test

Reporting group description: -

Reporting group title	Test

Reporting group description: -

Primary: 24hr Cough count

End point title	24hr Cough count

End point description:

End point type	Primary

End point timeframe:

24hr

End point values	Test	Test	Test	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	21	20	20	
Units: Coughs per hour				
number (not applicable)	14.63	16.68	18.23	

Statistical analyses

Statistical analysis title	p-value
Comparison groups	Test v Test v Test
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	Chi-squared

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The investigator or designee will question subjects about AEs and intercurrent illnesses at Baseline and at all subsequent visits since their last visit. The pertinent information will be recorded on the CRF.
Safety will be assessed through monitoring

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups

Reporting group title	Common cold
Reporting group description: -	
Reporting group title	Gastrointestinal symptoms
Reporting group description: -	
Reporting group title	Transient worsening cough
Reporting group description: -	

Serious adverse events	Common cold	Gastrointestinal symptoms	Transient worsening cough
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 21 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Common cold	Gastrointestinal symptoms	Transient worsening cough
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 21 (28.57%)	2 / 21 (9.52%)	2 / 21 (9.52%)
Gastrointestinal disorders			
Transient gastrointestinal symptoms	Additional description: Stomach cramps, slight reduction in appetite.		
subjects affected / exposed	0 / 21 (0.00%)	2 / 21 (9.52%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Respiratory, thoracic and mediastinal disorders			
Common cold	Additional description: 6 patients suffered with a common cold (trial took place over winter).		

subjects affected / exposed	6 / 21 (28.57%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	6	0	0
Transient worsening cough			
subjects affected / exposed	0 / 21 (0.00%)	0 / 21 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2

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? Yes

Date	Interruption	Restart date
29 May 2020	At this time our focus changed to COVID-19 research.	-

Notes:

Limitations and caveats

None reported