Clinical trial results:
A SINGLE-BLINDED RANDOMIZED, PLACEBO-CONTROLLED PHASE II TRIAL OF PROPHYLACTIC TREATMENT WITH ORAL AZITHROMYCIN VERSUS PLACEBO IN CANCER PATIENTS UNDERGOING ANTINEOPLASTIC TREATMENT DURING THE COVID-19 PANDEMIC

Summary

EudraCT number	2020-001327-13
Trial protocol	AT
Global end of trial date	14 June 2021

Results information

Result version number	v1 (current)
This version publication date	05 November 2022
First version publication date	05 November 2022

Trial information

Trial identification

Sponsor protocol code	OnCoVID19Trial

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04369365
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MedUniWien
Sponsor organisation address	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Marika Rosner, Med. Univ. Wien, +43 14040044450, marika.rosner@meduniwien.ac.at
Scientific contact	Matthias Preusser, Med. Univ. Wien, +43 14040044450, mattias.preusser@meduniwien.ac.at

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	30 March 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 March 2021
Global end of trial reached?	Yes
Global end of trial date	14 June 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Cumulative number of SARS-COV-2 infections as verified by PCR from routine nasal swabs performed every 28 days (symptomatic or asymptomatic) at week 12 after initiation of therapy

Protection of trial subjects:

no protection needed for this IMP

Background therapy:

no background therapy needed for this IMP

Evidence for comparator: -

Actual start date of recruitment	25 April 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	Austria: 63
Worldwide total number of subjects	63
EEA total number of subjects	63

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)	39
From 65 to 84 years	24
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited through the outpatient clinic, the daily clinic, and the inpatient ward of the Department of Internal Medicine I.

Pre-assignment

Screening details:

The screening was done on the basis of the screening criteria.

Period 1

Period 1 title	Overall period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Azithromycin
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Azithromycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

1500mg azithromycin once a week

Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

1500mg placebo once a week

Number of subjects in period 1	Azithromycin	Placebo
Started	32	31
Completed	24	25
Not completed	8	6
Consent withdrawn by subject	8	6

Baseline characteristics

Reporting groups

Reporting group title	Overall period

Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	63	63	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	39	39	
From 65-84 years	24	24	
85 years and over	0	0	
Age continuous Units: years			
median	59		
full range (min-max)	19 to 82	-	
Gender categorical Units: Subjects			
Female	39	39	
Male	24	24	

Subject analysis sets

Subject analysis set title	cumulative number of SARS-CoV-2 infections (both symptomatic a
Subject analysis set type	Per protocol

Subject analysis set description:

Kaplan-Meier plots, log-rank Tests

Reporting group values	cumulative number of SARS-CoV-2 infections (both symptomatic a		
Number of subjects	63		
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)	39		
From 65-84 years	24		
85 years and over	0		
Age continuous			
Units: years			
median	59		
full range (min-max)	19 to 82		
Gender categorical			
Units: Subjects			
Female	39		
Male	24		

End points

End points reporting groups

Reporting group title	Azithromycin
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Subject analysis set title	cumulative number of SARS-CoV-2 infections (both symptomatic a
Subject analysis set type	Per protocol
Subject analysis set description: Kaplan-Meier plots, log-rank Tests	

Primary: Cumulative number of SARS-CoV-2 infections (both symptomatic and asymptomatic)

End point title	Cumulative number of SARS-CoV-2 infections (both symptomatic and asymptomatic)
End point description:	
End point type	Primary
End point timeframe: after 12 weeks	

End point values	Azithromycin	Placebo	cumulative number of SARS-CoV-2 infections (both symptomatic a	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	32	31	63	
Units: 63	32	31	63	

Statistical analyses

Statistical analysis title	cumulative number of SARS-CoV-2 infections
Comparison groups	Placebo v Azithromycin
Number of subjects included in analysis	63
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	Chi-squared

Primary: Cumulative number of SARS-CoV-2 infections (both symptomatic and asymptomatic)

End point title	Cumulative number of SARS-CoV-2 infections (both

	symptomatic and asymptomatic)

End point description:

End point type	Primary

End point timeframe:
after 12 weeks

End point values	Azithromycin	Placebo	cumulative number of SARS-CoV-2 infections (both symptomatic a	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	32	31	63	
Units: 63	32	31	63	

Statistical analyses

Statistical analysis title	cumulative number of SARS-CoV-2 infections
Comparison groups	Azithromycin v Placebo
Number of subjects included in analysis	63
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	Chi-squared

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From the time of signing the informed consent through to the end of study visit.	
Assessment type	Systematic
Dictionary used	
Dictionary name	NCI CTCAE
Dictionary version	5.0
Reporting groups	
Reporting group title	Unspecific Adverse Events
Reporting group description: Toxicities were mainly mild and mostly unspecific.	

Serious adverse events	Unspecific Adverse Events		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 63 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Unspecific Adverse Events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 63 (44.44%)		
Cardiac disorders			
QTc prolongation			
subjects affected / exposed	14 / 63 (22.22%)		
occurrences (all)	14		
Hypertension			
subjects affected / exposed	2 / 63 (3.17%)		
occurrences (all)	2		
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 63 (1.59%)		
occurrences (all)	1		
Immune system disorders			

Fever subjects affected / exposed occurrences (all)	1 / 63 (1.59%) 1		
Gastrointestinal disorders Diarrhea subjects affected / exposed occurrences (all) Abdominal cramps subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Dysgeusia subjects affected / exposed occurrences (all)	 6 / 63 (9.52%) 6 2 / 63 (3.17%) 2 1 / 63 (1.59%) 1 1 / 63 (1.59%) 1		

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