



Clinical trial results:

A Phase II, randomized, double-blind, parallel group dose finding study of single oral doses of moxidectin in adults with scabies

Summary

EudraCT number	2019-001775-37
Trial protocol	FR AT
Global end of trial date	28 February 2022

Results information

Result version number	v1 (current)
This version publication date	16 March 2023
First version publication date	16 March 2023

Trial information

Trial identification

Sponsor protocol code	MDGH-MOX-2001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03905265
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Medicines Development for Global Health Limited
Sponsor organisation address	Level 1, 18 Kavanagh Street, Southbank, Australia,
Public contact	Clinical Project Manager, Medicines Development for Global Health, +61 399122400, MDGH-MOX-2001@medicinesdevelopment.com
Scientific contact	Clinical Project Manager, Medicines Development for Global Health, +61 399122400, MDGH-MOX-2001@medicinesdevelopment.com

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	28 February 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 February 2022
Global end of trial reached?	Yes
Global end of trial date	28 February 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of the trial were to identify an optimal dose of moxidectin for the treatment of scabies and evaluate the safety of moxidectin in adults infected with scabies.

Protection of trial subjects:

Approval for the conduct of the study was obtained from the Independent Ethics Committees associated with each study site before study commencement. The protocol, all material that was provided to the subjects such as the Informed Consent Form, subject information sheets and advertising text, and all amendments made to the protocol and/or consent forms after receipt of initial approval were submitted to the Independent Ethics Committee associated with each study site prior to use. The Investigators ensured that this study was conducted in full conformance with the protocol, the latest version of the Declaration of Helsinki (and its amendments), and with the requirements of national drug and data protection laws of the countries in which the research was conducted.

The Sponsor and the Investigators ensured strict adherence to the provisions of Good Clinical Practice (GCP) and all applicable and national regulations. The International Conference on Harmonization (ICH) guidelines was applied, at a minimum.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 August 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 7
Country: Number of subjects enrolled	France: 7
Country: Number of subjects enrolled	Australia: 8
Worldwide total number of subjects	22
EEA total number of subjects	14

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)	19
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in Australia and Europe. Screening commenced in January 2020. The last study visit occurred on 28 Feb 2022.

Pre-assignment

Screening details:

27 participants were screened.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	2 mg moxidectin

Arm description:

Participants received a single oral dose of 2 mg moxidectin on Day 0

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

Dosage and administration details:

Each participant received a single dose of moxidectin at the specified dose on Day 0, comprised of active study drug (moxidectin 2 mg tablets) and a sufficient quantity of placebo tablets to maintain the blind, up to a maximum of 18 tablets.

Arm title	8 mg moxidectin
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Arm description:

Participants received a single oral dose of 8 mg moxidectin on Day 0

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

Dosage and administration details:

Each participant received a single dose of moxidectin at the specified dose on Day 0, comprised of active study drug (moxidectin 2 mg tablets) and a sufficient quantity of placebo tablets to maintain the blind, up to a maximum of 18 tablets.

Arm title	20 mg moxidectin
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Arm description:

Participants received a single oral dose of 20 mg moxidectin on Day 0

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

Dosage and administration details:

Each participant received a single dose of moxidectin at the specified dose on Day 0, comprised of active study drug (moxidectin 2 mg tablets) and a sufficient quantity of placebo tablets to maintain the blind, up to a maximum of 18 tablets.

Arm title	36 mg moxidectin
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Arm description:

Participants received a single oral dose of 36 mg moxidectin on Day 0

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

Dosage and administration details:

Each participant received a single dose of moxidectin at the specified dose on Day 0, comprised of active study drug (moxidectin 2 mg tablets) and a sufficient quantity of placebo tablets to maintain the blind, up to a maximum of 18 tablets.

Number of subjects in period 1	2 mg moxidectin	8 mg moxidectin	20 mg moxidectin
Started	4	4	6
Completed	3	3	6
Not completed	1	1	0
Consent withdrawn by subject	1	1	-

Number of subjects in period 1	36 mg moxidectin
Started	8
Completed	8
Not completed	0
Consent withdrawn by subject	-

Baseline characteristics

Reporting groups

Reporting group title	2 mg moxidectin
Reporting group description:	
Participants received a single oral dose of 2 mg moxidectin on Day 0	
Reporting group title	8 mg moxidectin
Reporting group description:	
Participants received a single oral dose of 8 mg moxidectin on Day 0	
Reporting group title	20 mg moxidectin
Reporting group description:	
Participants received a single oral dose of 20 mg moxidectin on Day 0	
Reporting group title	36 mg moxidectin
Reporting group description:	
Participants received a single oral dose of 36 mg moxidectin on Day 0	

Reporting group values	2 mg moxidectin	8 mg moxidectin	20 mg moxidectin
Number of subjects	4	4	6
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	3	6
From 65-84 years	1	1	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	46.5	45.3	27.2
standard deviation	± 18.88	± 15.50	± 9.33
Gender categorical			
Units: Subjects			
Female	4	1	4
Male	0	3	2

Reporting group values	36 mg moxidectin	Total	
Number of subjects	8	22	
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)	7	19	
From 65-84 years	1	3	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	29.4		
standard deviation	± 17.26	-	
Gender categorical			
Units: Subjects			
Female	4	13	
Male	4	9	

Subject analysis sets

Subject analysis set title	Enrolled Set
Subject analysis set type	Full analysis

Subject analysis set description:

The Enrolled Set included all subjects who were randomized irrespective of whether they received the study drug.

Subject analysis set title	Per Protocol Analysis Set
Subject analysis set type	Per protocol

Subject analysis set description:

The Per Protocol Analysis Set (PPAS) included all subjects exposed to study drug without any major protocol deviations that could have confounded the assessment and/or interpretation of the analytic results. Subjects in the PPAS were analyzed according to the actual dose of study drug received regardless of their randomized dose group. In general, PPAS subjects with missing data for a specific analysis were excluded from that analysis.

Subject analysis set title	Safety Analysis Set
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Analysis Set (SfAS) included all subjects exposed to study drug. Subjects were analyzed according to the actual dose of study drug received regardless of their randomized dose group. Unless otherwise noted, the SfAS was used for all safety analyses.

Subject analysis set title	Pharmacokinetic Analysis Set
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The Pharmacokinetic (PK) Analysis Set included subjects in the Enrolled Analysis Set with at least one blood sample that was collected to assess moxidectin PK concentrations.

Reporting group values	Enrolled Set	Per Protocol Analysis Set	Safety Analysis Set
Number of subjects	22	15	22
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			
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Age continuous Units: years arithmetic mean standard deviation	34.8 ± 16.73	±	±
Gender categorical Units: Subjects			
Female Male			

Reporting group values	Pharmacokinetic Analysis Set		
Number of subjects	22		
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 standard deviation	±		
Gender categorical Units: Subjects			
Female Male			

End points

End points reporting groups

Reporting group title	2 mg moxidectin
Reporting group description:	
Participants received a single oral dose of 2 mg moxidectin on Day 0	
Reporting group title	8 mg moxidectin
Reporting group description:	
Participants received a single oral dose of 8 mg moxidectin on Day 0	
Reporting group title	20 mg moxidectin
Reporting group description:	
Participants received a single oral dose of 20 mg moxidectin on Day 0	
Reporting group title	36 mg moxidectin
Reporting group description:	
Participants received a single oral dose of 36 mg moxidectin on Day 0	
Subject analysis set title	Enrolled Set
Subject analysis set type	Full analysis
Subject analysis set description:	
The Enrolled Set included all subjects who were randomized irrespective of whether they received the study drug.	
Subject analysis set title	Per Protocol Analysis Set
Subject analysis set type	Per protocol
Subject analysis set description:	
The Per Protocol Analysis Set (PPAS) included all subjects exposed to study drug without any major protocol deviations that could have confounded the assessment and/or interpretation of the analytic results. Subjects in the PPAS were analyzed according to the actual dose of study drug received regardless of their randomized dose group. In general, PPAS subjects with missing data for a specific analysis were excluded from that analysis.	
Subject analysis set title	Safety Analysis Set
Subject analysis set type	Safety analysis
Subject analysis set description:	
The Safety Analysis Set (SfAS) included all subjects exposed to study drug. Subjects were analyzed according to the actual dose of study drug received regardless of their randomized dose group. Unless otherwise noted, the SfAS was used for all safety analyses.	
Subject analysis set title	Pharmacokinetic Analysis Set
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
The Pharmacokinetic (PK) Analysis Set included subjects in the Enrolled Analysis Set with at least one blood sample that was collected to assess moxidectin PK concentrations.	

Primary: Subject Incidence of Treatment-Emergent Adverse Events

End point title	Subject Incidence of Treatment-Emergent Adverse Events ^[1]
End point description:	
Treatment emergent adverse events (TEAEs) were defined as adverse events that started or worsened, on or after the start of the administration of investigational product.	
End point type	Primary
End point timeframe:	
Up to and including Week 12.	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Study data was analyzed in a descriptive manner and sample size was not based on formal power considerations with respect to statistical hypothesis testing.

End point values	2 mg moxidectin	8 mg moxidectin	20 mg moxidectin	36 mg moxidectin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	6	8
Units: Number of subjects				
Any TEAE	4	4	6	8
Serious TEAEs	0	0	0	1
Serious study-drug related TEAEs	0	0	0	0
TEAEs leading to withdrawal	0	0	0	0
TEAEs leading to death	0	0	0	0

End point values	Safety Analysis Set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: Number of subjects				
Any TEAE	22			
Serious TEAEs	1			
Serious study-drug related TEAEs	0			
TEAEs leading to withdrawal	0			
TEAEs leading to death	0			

Statistical analyses

No statistical analyses for this end point

Primary: Time to death of adult scabies mites

End point title	Time to death of adult scabies mites ^[2]
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End point description:

Efficacy at Day 28 will be determined by death of the mites, defined as the degradation (loss of internal and/or external anatomic structures) of the adult mite observed by reflectance confocal microscopy.

End point type	Primary
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End point timeframe:

Mites were assessed by reflectance confocal microscopy (RCM) at Hours 4, 8, 24, 48 and 72 and Days 7, 14 and 28 in not less than two lesions nominated pre-treatment. No subject had more than 2 mites assessed by RCM.

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Study data was analyzed in a descriptive manner and sample size was not based on formal power considerations with respect to statistical hypothesis testing.

End point values	2 mg moxidectin	8 mg moxidectin	20 mg moxidectin	36 mg moxidectin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	4	7
Units: hours				
arithmetic mean (standard deviation)	671.3 (± 0)	215.1 (± 219.4)	229.2 (± 128.6)	251.7 (± 196.6)

End point values	Per Protocol Analysis Set			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: hours				
arithmetic mean (standard deviation)	266.4 (± 204.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Severity of Treatment Emergent Adverse Events

End point title	Severity of Treatment Emergent Adverse Events ^[3]
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End point description:

Treatment emergent adverse events (TEAEs) were defined as adverse events that started, or worsened, on or after the start of the administration of investigational product. If a subject experienced more than one TEAE, the subject is counted once at the most severe event.

End point type	Primary
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End point timeframe:

Up to and including Week 12.

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Study data was analyzed in a descriptive manner and sample size was not based on formal power considerations with respect to statistical hypothesis testing.

End point values	2 mg moxidectin	8 mg moxidectin	20 mg moxidectin	36 mg moxidectin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	6	8
Units: Number of subjects				
Grade 1 TEAEs	1	1	4	5
Grade 2 TEAEs	3	3	2	3
Grade 3 TEAEs	0	0	0	0
Grade 4 TEAEs	0	0	0	0

End point values	Safety Analysis Set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: Number of subjects				
Grade 1 TEAEs	11			
Grade 2 TEAEs	11			
Grade 3 TEAEs	0			

Grade 4 TEAEs	0			
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Statistical analyses

No statistical analyses for this end point

Primary: Proportion of Subjects with 100% Dead Adult Scabies Mites on Day 28

End point title	Proportion of Subjects with 100% Dead Adult Scabies Mites on Day 28 ^[4]
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End point description:

Efficacy at Day 28 will be determined by death of the mites, defined as the degradation (loss of internal and/or external anatomic structures) of the adult mite observed by reflectance confocal microscopy.

End point type	Primary
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End point timeframe:

Mites were assessed by reflectance confocal microscopy (RCM) at Hours 4, 8, 24, 48 and 72 and Days 7, 14 and 28 in not less than two lesions nominated pre-treatment. No subject had more than 2 mites assessed by RCM.

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Study data was analyzed in a descriptive manner and sample size was not based on formal power considerations with respect to statistical hypothesis testing.

End point values	2 mg moxidectin	8 mg moxidectin	20 mg moxidectin	36 mg moxidectin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	4	7
Units: Percentage of subjects	0	100	100	100

End point values	Per Protocol Analysis Set			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Percentage of subjects	93			

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the Concentration-Time Curve over 28 days (AUC0-28) of moxidectin

End point title	Area under the Concentration-Time Curve over 28 days (AUC0-28) of moxidectin
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End point description:

Pharmacokinetic parameters were calculated were derived using non-compartmental methods. AUC

calculation method was linear up log down.

End point type	Secondary
End point timeframe:	
Nominal time of PK sample collection was Pre-dose, 2hours (h), 3h, 4h, 8h, Day 1 (24h), Day 2 (48h), Day 3 (72h), Day 7 (168h), Day 14 (336h) and Day 28 (672h)	

End point values	2 mg moxidectin	8 mg moxidectin	20 mg moxidectin	36 mg moxidectin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	6	8
Units: hr*ng/ml				
geometric mean (geometric coefficient of variation)	408 (± 82.5)	1970 (± 30.0)	4670 (± 41.1)	7430 (± 37.6)

End point values	Pharmacokinetic Analysis Set			
Subject group type	Subject analysis set			
Number of subjects analysed	0 ^[5]			
Units: hr*ng/ml				
geometric mean (geometric coefficient of variation)	()			

Notes:

[5] - AUC0-28 was not calculated for all subjects

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum observed plasma concentration of moxidectin

End point title	Maximum observed plasma concentration of moxidectin
End point description:	
Pharmacokinetic parameters were calculated were derived using non-compartmental methods.	
End point type	Secondary
End point timeframe:	
Nominal time of PK sample collection was Pre-dose, 2hours (h), 3h, 4h 8h, Day 1 (24h), Day 2 (48h), Day 3 (72h), Day 7 (168h), Day 14 (336h) and Day 28 (672h)	

End point values	2 mg moxidectin	8 mg moxidectin	20 mg moxidectin	36 mg moxidectin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	6	8
Units: ng/mL				
geometric mean (geometric coefficient of variation)	21.0 (± 47.1)	73.5 (± 42.0)	207 (± 44.9)	277 (± 26.9)

End point values	Pharmacokinetic Analysis Set			
Subject group type	Subject analysis set			
Number of subjects analysed	0 ^[6]			
Units: ng/mL				
geometric mean (geometric coefficient of variation)	()			

Notes:

[6] - Overall Cmax was not determined

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 0 to Week 12, inclusive.

Adverse event reporting additional description:

Treatment-emergent adverse events (TEAEs) were defined as adverse events that started or worsened on or after the start of investigational product administration. TEAEs that occurred in more than 5% of subjects overall are reported. The most commonly occurring TEAEs are defined as those occurring in two or more subjects (5%) overall.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.1
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Reporting groups

Reporting group title	2 mg moxidectin
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Reporting group description:

Participants received a single oral dose of 2 mg moxidectin on Day 0

Reporting group title	8 mg moxidectin
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Reporting group description:

Participants received a single oral dose of 8 mg moxidectin on Day 0

Reporting group title	20 mg moxidectin
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Reporting group description:

Participants received a single oral dose of 20 mg moxidectin on Day 0

Reporting group title	36 mg moxidectin
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Reporting group description:

Participants received a single oral dose of 36 mg moxidectin on Day 0

Reporting group title	Overall
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Reporting group description:

All subjects

Serious adverse events	2 mg moxidectin	8 mg moxidectin	20 mg moxidectin
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Uterine haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	36 mg moxidectin	Overall	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 8 (12.50%)	1 / 22 (4.55%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 8 (12.50%)	1 / 22 (4.55%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Uterine haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	1 / 22 (4.55%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	2 mg moxidectin	8 mg moxidectin	20 mg moxidectin
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	4 / 4 (100.00%)	6 / 6 (100.00%)
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Nausea			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 4 (25.00%) 1	1 / 6 (16.67%) 1
Skin and subcutaneous tissue disorders Pruritus subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Eczema subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	2 / 4 (50.00%) 2	0 / 6 (0.00%) 0
Rash papular subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 2	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Infections and infestations Acarodermatitis subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 2	3 / 4 (75.00%) 3	4 / 6 (66.67%) 5

Non-serious adverse events	36 mg moxidectin	Overall	
Total subjects affected by non-serious adverse events subjects affected / exposed	8 / 8 (100.00%)	22 / 22 (100.00%)	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 3	4 / 22 (18.18%) 5	
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	2 / 22 (9.09%) 2	
Nausea subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	2 / 22 (9.09%) 2	
Skin and subcutaneous tissue disorders Pruritus			

subjects affected / exposed occurrences (all)	3 / 8 (37.50%) 3	4 / 22 (18.18%) 4	
Eczema subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	3 / 22 (13.64%) 3	
Rash papular subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	2 / 22 (9.09%) 3	
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	2 / 22 (9.09%) 2	
Infections and infestations Acarodermatitis subjects affected / exposed occurrences (all)	5 / 8 (62.50%) 6	14 / 22 (63.64%) 16	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 June 2020	The protocol was amended to permit ongoing data review by a Protocol Steering Committee and provision for opening the 36 mg moxidectin dose cohort and/or closing recruitment to any of the moxidectin dose cohorts. The amendment also contained provisions for modifying scheduled procedures due to the ongoing novel SARS-CoV-2 (COVID 19) pandemic.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Small number of subjects, especially in the Per-Protocol Analysis set, confounds interpretation of some study results.
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Notes: