



Clinical trial results: Hypertrophic CARdiomyopathy symptom release by alpha stimulant MIDOdrene

Summary

EudraCT number	2015-003521-34
Trial protocol	FR
Global end of trial date	06 July 2016

Results information

Result version number	v1 (current)
This version publication date	18 September 2026
First version publication date	18 September 2026

Trial information

Trial identification

Sponsor protocol code	CHUBX 2015/14
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02590809
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CHU de Bordeaux
Sponsor organisation address	12 rue dubernat, Talence, France,
Public contact	Pr LAFITTE Stephane Service médico-chirurgical des valvulopathies et cardiomyopathies - Chirurgie, CHU de bordeaux, stephane.lafitte@chu-bordeaux.fr
Scientific contact	Pr LAFITTE Stephane Service médico-chirurgical des valvulopathies et cardiomyopathies - Chirurgie, CHU de bordeaux, stephane.lafitte@chu-bordeaux.fr

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	06 July 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 July 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the results of the 6-minute walk test (6MWT) at 2 weeks (D15), in HCM patients with exercise obstruction, between two parallel groups of midodrine hydrochloride treatment, placebo.

Protection of trial subjects:

NI-CE avec MR

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 October 2015
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	France: 38
Worldwide total number of subjects	38
EEA total number of subjects	38

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)	25
From 65 to 84 years	13
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Date of first inclusion: 07/10/2015

Date of last inclusion: 07/06/2016

One center in France participated on the study

Pre-assignment

Screening details:

- Adults aged 18-80 years of both sexes
- Patients with typical or atypical hypertrophic cardiomyopathy diagnosed by cardiac imaging (echocardiography and MRI) and/or genetic testing or family history
- Treadmill obstruction (sub-aortic obstruction > 50 mmHg measured in continuous Doppler aligned with aortic ejection)
- Positive response

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, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	Chlorydrate of midodrine group

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Treatment BX1514M
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

X mg x 3 /day of BX1514M for 15 days. Dosage will be then adapted, depending on symptoms release and walk distance test results for another 15 days period.

Arm title	Placebo group
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Arm description: -

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

Dosage and administration details:

Placebo will be given orally for 30 days

Number of subjects in period 1	Chlorydrate of midodrine group	Placebo group
Started	18	20
Completed	18	20

Baseline characteristics

Reporting groups

Reporting group title	Chlorydrate of midodrine group
Reporting group description: -	
Reporting group title	Placebo group
Reporting group description: -	

Reporting group values	Chlorydrate of midodrine group	Placebo group	Total
Number of subjects	18	20	38
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	55.2	56.7	
standard deviation	± 12.3	± 11.0	-
Gender categorical Units: Subjects			
Female	8	6	14
Male	10	14	24

End points

End points reporting groups

Reporting group title	Chlorydrate of midodrine group
Reporting group description: -	
Reporting group title	Placebo group
Reporting group description: -	

Primary: Distance travelled, in metres, in the 6-minute walk test (6MWT) at 15 days

End point title	Distance travelled, in metres, in the 6-minute walk test (6MWT) at 15 days
End point description:	
End point type	Primary
End point timeframe:	
At 15 days	

End point values	Chlorydrate of midodrine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	19		
Units: meter				
arithmetic mean (standard deviation)	529.6 (± 81.3)	551.4 (± 109.0)		

Statistical analyses

Statistical analysis title	Description of the distance covered at D15
Comparison groups	Chlorydrate of midodrine group v Placebo group
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5046
Method	t-test, 2-sided

Secondary: Distance travelled, in metres, during the 6-minute walk test (6MWT) at D30

End point title	Distance travelled, in metres, during the 6-minute walk test (6MWT) at D30
End point description:	

End point type	Secondary
End point timeframe:	
At 30 days	

End point values	Chlorydrate of midodrine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	18		
Units: meter				
arithmetic mean (standard deviation)	547.3 (± 91.8)	576.3 (± 100.5)		

Statistical analyses

Statistical analysis title	Description of the distance covered at D30
Comparison groups	Chlorydrate of midodrine group v Placebo group
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3964
Method	t-test, 2-sided

Secondary: Measurement of intraventricular obstruction at rest, by Doppler evaluation of the intraventricular obstruction parameter, at D15

End point title	Measurement of intraventricular obstruction at rest, by Doppler evaluation of the intraventricular obstruction parameter, at D15
End point description:	
Maximum obstruction gradient at D15 is measured during resting echography	
End point type	Secondary
End point timeframe:	
At 15 days	

End point values	Chlorydrate of midodrine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	18		
Units: millimeter(s) of mercury				
arithmetic mean (standard deviation)	49.8 (± 45.4)	34.9 (± 30.2)		

Statistical analyses

Statistical analysis title	Description of intraventricular obstruction at D15
Comparison groups	Chlorydrate of midodrine group v Placebo group
Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6318
Method	Wilcoxon (Mann-Whitney)

Secondary: Measurement of intraventricular obstruction during exercise, by Doppler evaluation of the intraventricular obstruction parameter, at D15

End point title	Measurement of intraventricular obstruction during exercise, by Doppler evaluation of the intraventricular obstruction parameter, at D15
End point description:	Maximum obstruction gradient at D15 is measured during the exercise echography on a mat at rest
End point type	Secondary
End point timeframe:	At 15 days

End point values	Chlorydrate of midodrine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	19		
Units: millimeter(s) of mercury				
arithmetic mean (standard deviation)	59.2 (± 46.2)	36.9 (± 23.2)		

Statistical analyses

Statistical analysis title	Description of intraventricular obstruction at D15
Comparison groups	Chlorydrate of midodrine group v Placebo group

Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4447
Method	Wilcoxon (Mann-Whitney)

Secondary: Measurement of intraventricular obstruction at rest, by Doppler evaluation of the intraventricular obstruction parameter, at D30

End point title	Measurement of intraventricular obstruction at rest, by Doppler evaluation of the intraventricular obstruction parameter, at D30
End point description:	Maximum obstruction gradient at D30 is measured during resting echography
End point type	Secondary
End point timeframe:	At 30 days

End point values	Chlorydrate of midodrine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	18		
Units: millimeter(s) of mercury				
arithmetic mean (standard deviation)	50.9 (± 42.4)	24.4 (± 17.5)		

Statistical analyses

Statistical analysis title	Description of intraventricular obstruction at D30
Comparison groups	Chlorydrate of midodrine group v Placebo group
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1637
Method	Wilcoxon (Mann-Whitney)

Secondary: Measurement of intraventricular obstruction during exercise, by Doppler evaluation of the intraventricular obstruction parameter, at D30

End point title	Measurement of intraventricular obstruction during exercise, by Doppler evaluation of the intraventricular obstruction parameter, at D30
End point description:	Maximum obstruction gradient at D30 is measured during the stress echography on a mat at rest.
End point type	Secondary

End point timeframe:

At 30 days

End point values	Chlorydrate of midodrine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	17		
Units: millimeter(s) of mercury				
arithmetic mean (standard deviation)	53.2 ($\pm$ 36.8)	42.5 ($\pm$ 25.4)		

Statistical analyses

Statistical analysis title	Description of intraventricular obstruction at D30
Comparison groups	Chlorydrate of midodrine group v Placebo group
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7062
Method	Wilcoxon (Mann-Whitney)

Secondary: NYHA functional class at D15

End point title	NYHA functional class at D15
End point description:	
End point type	Secondary
End point timeframe:	
At 15 days	

End point values	Chlorydrate of midodrine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	18		
Units: percent				
number (not applicable)				
Class 1	16.7	11.1		
Class 2	61.1	61.1		
Class 3	16.7	27.8		
Class 4	5.6	0		

Statistical analyses

No statistical analyses for this end point

Secondary: NYHA functional class at D30

End point title NYHA functional class at D30

End point description:

End point type Secondary

End point timeframe:

At 30 days

End point values	Chlorydrate of midodrine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	16		
Units: percent				
number (not applicable)				
Class 1	20.0	18.8		
Class 2	53.3	68.8		
Class 3	26.7	12.5		

Statistical analyses

No statistical analyses for this end point

Secondary: The CCS pain score at D30

End point title The CCS pain score at D30

End point description:

End point type Secondary

End point timeframe:

At 30 days

End point values	Chlorydrate of midodrine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	16		
Units: percent				
number (not applicable)				
Class I	80	75		
Class II	20	25		

Statistical analyses

No statistical analyses for this end point

Secondary: B-type natriuretic peptide (BNP) at D30

End point title	B-type natriuretic peptide (BNP) at D30
End point description:	
End point type	Secondary
End point timeframe:	
At 30 days	

End point values	Chlorydrate of midodrine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	18		
Units: picogram(s)/millilitre				
arithmetic mean (standard deviation)	383.4 (± 548.3)	279.2 (± 310.5)		

Statistical analyses

Statistical analysis title	Description of BNP
Comparison groups	Chlorydrate of midodrine group v Placebo group
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7312
Method	Wilcoxon (Mann-Whitney)

Secondary: Echocardiography - Blood pressure, resting SBP at D30

End point title	Echocardiography - Blood pressure, resting SBP at D30
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End point description:

End point type	Secondary
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End point timeframe:

At 30 days

End point values	Chlorydrate of midodrine group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: millimeter(s) of mercury				
arithmetic mean (standard deviation)	119.2 (± 15.9)	119.3 (± 17.1)		

Statistical analyses

Statistical analysis title	Description of the blood pressure
Comparison groups	Chlorydrate of midodrine group v Placebo group
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9872
Method	t-test, 2-sided

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Overall study

Adverse event reporting additional description:

These adverse events are described by Preferred Terms (PT)

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.1
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Reporting groups

Reporting group title	Chlorydrate of midodrine group
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Reporting group description: -

Reporting group title	Placebo group
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Reporting group description: -

Serious adverse events	Chlorydrate of midodrine group	Placebo group	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 18 (5.56%)	1 / 20 (5.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
Cardiac failure (10007554)			
subjects affected / exposed	1 / 18 (5.56%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia (10002034)			
subjects affected / exposed	1 / 18 (5.56%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Haemorrhoids (10019022)			
subjects affected / exposed	1 / 18 (5.56%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			

Acute pulmonary oedema (10001029)			
subjects affected / exposed	0 / 18 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea (10013968)			
subjects affected / exposed	1 / 18 (5.56%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Chlorydrate of midodrine group	Placebo group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 18 (55.56%)	8 / 20 (40.00%)	
Investigations			
Brain natriuretic peptide increased (10053405)			
subjects affected / exposed	0 / 18 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Blood creatinine increased (10005483)			
subjects affected / exposed	1 / 18 (5.56%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Hypotension (10021097)			
subjects affected / exposed	0 / 18 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Hot flush (10060800)			
subjects affected / exposed	1 / 18 (5.56%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			
Therapy cessation (10065154)			
subjects affected / exposed	0 / 18 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Cardiac disorders			

Palpitations (10033557) subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 20 (0.00%) 0	
Nervous system disorders			
Headache (10019211) subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 20 (5.00%) 1	
Dizziness (10013573) subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	2 / 20 (10.00%) 2	
Presyncope (10036653) subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 20 (0.00%) 0	
Paraesthesia (10033775) subjects affected / exposed occurrences (all)	4 / 18 (22.22%) 4	0 / 20 (0.00%) 0	
Migraine (10027599) subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	1 / 20 (5.00%) 1	
General disorders and administration site conditions			
Chills (10008531) subjects affected / exposed occurrences (all)	3 / 18 (16.67%) 3	0 / 20 (0.00%) 0	
Fatigue (10016256) subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 20 (0.00%) 0	
Malaise (10025482) subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 20 (5.00%) 1	
Influenza like illness (10022004) subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 20 (0.00%) 0	
Gastrointestinal disorders			
Vomiting (10047700) subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 20 (5.00%) 1	

Respiratory, thoracic and mediastinal disorders Dyspnoea (10013968) subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 20 (5.00%) 1	
Skin and subcutaneous tissue disorders Urticaria (10046735) subjects affected / exposed occurrences (all) Pruritus (10037087) subjects affected / exposed occurrences (all) Piloerection (10035039) subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1 1 / 18 (5.56%) 1 4 / 18 (22.22%) 4	0 / 20 (0.00%) 0 0 / 20 (0.00%) 0 0 / 20 (0.00%) 0	
Psychiatric disorders Agitation (10001497) subjects affected / exposed occurrences (all) Nervousness (10029216) subjects affected / exposed occurrences (all) Libido disorder (10061221) subjects affected / exposed occurrences (all) Insomnia (10022437) subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1 1 / 18 (5.56%) 1 0 / 18 (0.00%) 0 0 / 18 (0.00%) 0	0 / 20 (0.00%) 0 0 / 20 (0.00%) 0 1 / 20 (5.00%) 1 2 / 20 (10.00%) 2	
Infections and infestations Acarodermatitis (10063409) subjects affected / exposed occurrences (all) Gastroenteritis (10017888) subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0 1 / 18 (5.56%) 1	1 / 20 (5.00%) 1 0 / 20 (0.00%) 0	

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/26898633>