Clinical trial results:
Beta-agonist Efficacy and Tolerability as Adjuvant therapy in Myasthenia Gravis

Summary

EudraCT number	2019-000895-40
Trial protocol	DK
Global end of trial date	30 December 2024

Results information

Result version number	v1 (current)
This version publication date	13 March 2026
First version publication date	13 March 2026

Trial information

Trial identification

Sponsor protocol code	BETA-MG-01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03914638
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle Juul-Jensens Boulevard, 8200 Aarhus N, Denmark,
Public contact	Jan L. S. Thomsen, Aarhus University Hospital, jathms@rm.dk
Scientific contact	Jan L. S. Thomsen, Aarhus University Hospital, jathms@rm.dk

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	20 October 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 December 2024
Global end of trial reached?	Yes
Global end of trial date	30 December 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the efficacy and tolerability of oral Salbutamol as adjuvant therapy in patients with generalized myasthenia gravis on stable medications with residual symptoms.

Protection of trial subjects:

Follow-up

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 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	Denmark: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	23
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

June 2019 to august 2024 at Aarhus, Aalborg and Odense

Pre-assignment

Screening details:

44 screened, 37 assessed for eligibility, 30 eligible.

Period 1

Period 1 title	Period 1 (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Blinding implementation details:

Active and placebo encapsulated in identical caps.

Arms

Are arms mutually exclusive?	Yes
Arm title	Salbutamol

Arm description: -

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

Dosage and administration details:

4 mg. three times daily

Arm title	Placebo

Arm description: -

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

Dosage and administration details:

1 capsule three times daily

Number of subjects in period 1	Salbutamol	Placebo
Started	15	15
Completed	13	15
Not completed	2	0
Adverse event, non-fatal	2	-

Baseline characteristics

End points

End points reporting groups	
Reporting group title	Salbutamol
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: QOL15	
End point title	QOL15
End point description:	
End point type	Primary
End point timeframe:	
Baseline to week 8.	

End point values	Salbutamol	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: -3,9				
number (confidence interval 95%)	-4.7 (-6.6 to -2.7)	-0.8 (-2.8 to 1.2)		

Statistical analyses

Statistical analysis title	Mixed effects
Statistical analysis description:	
Mixed effects linear regression with treatment, visit, treatment-by-visit interaction, sequence and period as fixed effects and subject as random effect.	
Comparison groups	Salbutamol v Placebo
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.7
upper limit	-1.1

Variability estimate	Standard deviation

Secondary: QMG

End point title	QMG

End point description:

End point type	Secondary

End point timeframe:

Baseline to week 8

End point values	Salbutamol	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: -3,0				
number (confidence interval 95%)	-2.6 (-3.4 to -1.7)	0.4 (-0.4 to 1.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: MGC

End point title	MGC

End point description:

End point type	Secondary

End point timeframe:

Baseline to week 8

End point values	Salbutamol	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: -1,9				
number (confidence interval 95%)	-2.9 (-4.1 to -1.7)	-1.0 (-2.2 to 0.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: MG-ADL

End point title	MG-ADL

End point description:

End point type	Secondary

End point timeframe:

Baseline to week 8

End point values	Salbutamol	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: -1,0				
number (confidence interval 95%)	-1.4 (-2.0 to -0.7)	-0.4 (-1.0 to 0.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Neuro-QoL

End point title	Neuro-QoL

End point description:

End point type	Secondary

End point timeframe:

Baseline to week 8

End point values	Salbutamol	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: -7,8				
number (confidence interval 95%)	-8.9 (-12.0 to -5.7)	-1.1 (-4.2 to 2.1)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Baseline to week 8 in both treatment periods.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: See publication on adverse events. This EudraCT system is not set-up to manage cross-over designs. There were no serious adverse events.
Palpitations 12 (salbutamol) / 3 (placebo)
Hypertension 2(salbutamol) / 5 (placebo)
Tremor 16 (salbutamol) / 0 (placebo)
Head 7 (salbutamol) / 3 (placebo)

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
02 December 2019	Covid-19	-

Notes:

Limitations and caveats

None reported