



Clinical trial results:

Combined effects of potassium, nitrate and sodium on blood pressure in patients with hypertension

Summary

EudraCT number	2021-003407-17
Trial protocol	DK
Global end of trial date	24 May 2024

Results information

Result version number	v1 (current)
This version publication date	22 November 2025
First version publication date	22 November 2025

Trial information

Trial identification

Sponsor protocol code	CLD-1-2021
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Regionshospitalet Gødstrup
Sponsor organisation address	Hospitalsparken 15, Herning, Denmark, 7400
Public contact	Camilla Lundgreen Duus, University Clinic in Nephrology and Hypertension, 0045 78432390, camduu@rm.dk
Scientific contact	Camilla Lundgreen Duus, University Clinic in Nephrology and Hypertension, 0045 78432390, camduu@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	01 August 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 May 2024
Global end of trial reached?	Yes
Global end of trial date	24 May 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is investigating the effect of dietary potassium, nitrate and salt on blood pressure in patients with essential hypertension

Protection of trial subjects:

All patients had direct phone number to a medical doctor during the entire study, and could contact her 24/7. If symptoms occurred and blood pressure was high, patients were excluded from the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 July 2022
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	Denmark: 92
Worldwide total number of subjects	92
EEA total number of subjects	92

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)	45
From 65 to 84 years	47
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from local newspapers, local general practitioners or from participants in previous studies in our department.

Pre-assignment

Screening details:

123 participants were screened, 111 included, 96 randomized and 90 completed the study. The screening process consisted of medical history, medical examination, blood pressure measurement, ECG, urine dip-stick, urine albumine/creatinine-ratio, blood samples (creatinine, eGFR, Na, K, Hemoglobin, albumin, ALAT, INR).

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	Group A

Arm description:

Low sodium (90 mmol), High potassium (125 mmol), low nitrate

Arm type	Experimental
Investigational medicinal product name	Potassium chloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use

Dosage and administration details:

1500 mg x 2

Investigational medicinal product name	Potassium chloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use

Dosage and administration details:

1500 mg x 2

Arm title	Group B
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Arm description:

High sodium (210 mmol), high potassium (125 mmol), low nitrate

Arm type	Experimental
Investigational medicinal product name	Potassium chloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use

Dosage and administration details:

1500 mg x 2

Investigational medicinal product name	Sodium chloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use
Dosage and administration details:	
7,5 g/day	
Arm title	Group C
Arm description:	
High sodium (210 mmol), high potassium (125 mmol), high nitrate (13 mmol)	
Arm type	Experimental
Investigational medicinal product name	Potassium chloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use
Dosage and administration details:	
1500 mg x 2	
Investigational medicinal product name	Sodium chloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use
Dosage and administration details:	
7,5 g/day	
Investigational medicinal product name	Beetroot juice with nitrate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Enteral use
Dosage and administration details:	
75 ml beetroot juice with 6,5 mmol nitrate x 2 per day.	
Arm title	Group D
Arm description:	
Low sodium (90 mmol), High potassium (125 mmol), high nitrate (13 mmol)	
Arm type	Experimental
Investigational medicinal product name	Potassium chloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use
Dosage and administration details:	
1500 mg x 2	
Investigational medicinal product name	Beetroot juice with nitrate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Enteral use
Dosage and administration details:	
75 ml beetroot juice with 6,5 mmol nitrate x 2 per day.	
Arm title	Group E

Arm description:	
Low sodium (90 mmol), low potassium (85 mmol), low nitrate	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Group F
Arm description:	
High sodium (210 mmol), high potassium (125 mmol), low nitrate	
Arm type	Experimental
Investigational medicinal product name	Sodium chloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use
Dosage and administration details:	
7,5 g/day	
Investigational medicinal product name	Potassium chloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use
Dosage and administration details:	
1500 mg x 2	
Arm title	Group G
Arm description:	
High sodium (210 mmol), low potassium (85 mmol), high nitrate (13 mmol)	
Arm type	Experimental
Investigational medicinal product name	Beetroot juice with nitrate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Enteral use
Dosage and administration details:	
75 ml beetroot juice with 6,5 mmol nitrate x 2 per day.	
Investigational medicinal product name	Sodium chloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Enteral use
Dosage and administration details:	
7,5 g/day	
Arm title	Group H
Arm description:	
Low sodium (90 mmol), low potassium (85 mmol), high nitrate (13 mmol)	
Arm type	Experimental
Investigational medicinal product name	Beetroot juice with nitrate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Enteral use
Dosage and administration details:	
75 ml beetroot juice with 6,5 mmol nitrate x 2 per day.	

Number of subjects in period 1	Group A	Group B	Group C
Started	11	11	12
Completed	11	11	12
Not completed	0	0	0
Adverse event, non-fatal	-	-	-

Number of subjects in period 1	Group D	Group E	Group F
Started	11	11	12
Completed	11	11	12
Not completed	0	0	0
Adverse event, non-fatal	-	-	-

Number of subjects in period 1	Group G	Group H
Started	12	12
Completed	11	11
Not completed	1	1
Adverse event, non-fatal	1	1

Baseline characteristics

Reporting groups

Reporting group title	Group A
Reporting group description: Low sodium (90 mmol), High potassium (125 mmol), low nitrate	
Reporting group title	Group B
Reporting group description: High sodium (210 mmol), high potassium (125 mmol), low nitrate	
Reporting group title	Group C
Reporting group description: High sodium (210 mmol), high potassium (125 mmol), high nitrate (13 mmol)	
Reporting group title	Group D
Reporting group description: Low sodium (90 mmol), High potassium (125 mmol), high nitrate (13 mmol)	
Reporting group title	Group E
Reporting group description: Low sodium (90 mmol), low potassium (85 mmol), low nitrate	
Reporting group title	Group F
Reporting group description: High sodium (210 mmol), high potassium (125 mmol), low nitrate	
Reporting group title	Group G
Reporting group description: High sodium (210 mmol), low potassium (85 mmol), high nitrate (13 mmol)	
Reporting group title	Group H
Reporting group description: Low sodium (90 mmol), low potassium (85 mmol), high nitrate (13 mmol)	

Reporting group values	Group A	Group B	Group C
Number of subjects	11	11	12
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	64.1	67.2	65.1
standard deviation	± 8.5	± 5.6	± 3.5

Gender categorical Units: Subjects			
Female	9	6	8
Male	2	5	4

Reporting group values	Group D	Group E	Group F
Number of subjects	11	11	12
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	60.2	61.4	63.6
standard deviation	± 8.1	± 9.8	± 10.1
Gender categorical Units: Subjects			
Female	4	4	4
Male	7	7	8

Reporting group values	Group G	Group H	Total
Number of subjects	12	12	92
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			0 0 0 0 0 0 0 0
Age continuous Units: years			
arithmetic mean	62.6	62.5	-
standard deviation	± 9	± 7.9	-
Gender categorical Units: Subjects			
Female	4	6	45
Male	8	6	47

End points

End points reporting groups

Reporting group title	Group A
Reporting group description: Low sodium (90 mmol), High potassium (125 mmol), low nitrate	
Reporting group title	Group B
Reporting group description: High sodium (210 mmol), high potassium (125 mmol), low nitrate	
Reporting group title	Group C
Reporting group description: High sodium (210 mmol), high potassium (125 mmol), high nitrate (13 mmol)	
Reporting group title	Group D
Reporting group description: Low sodium (90 mmol), High potassium (125 mmol), high nitrate (13 mmol)	
Reporting group title	Group E
Reporting group description: Low sodium (90 mmol), low potassium (85 mmol), low nitrate	
Reporting group title	Group F
Reporting group description: High sodium (210 mmol), high potassium (125 mmol), low nitrate	
Reporting group title	Group G
Reporting group description: High sodium (210 mmol), low potassium (85 mmol), high nitrate (13 mmol)	
Reporting group title	Group H
Reporting group description: Low sodium (90 mmol), low potassium (85 mmol), high nitrate (13 mmol)	

Primary: Change in systolic 24-hour blood pressure

End point title	Change in systolic 24-hour blood pressure
End point description:	
End point type	Primary
End point timeframe:	
One week	

End point values	Group A	Group B	Group C	Group D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	11	12	11
Units: mmHg				
arithmetic mean (standard deviation)	-7 (\pm 7)	-1 (\pm 8)	5 (\pm 8)	-6 (\pm 5)

End point values	Group E	Group F	Group G	Group H
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	11
Units: mmHg				
arithmetic mean (standard deviation)	-8 (\pm 9)	-2 (\pm 7)	-2 (\pm 9)	-8 (\pm 9)

Statistical analyses

Statistical analysis title	Fisher's exact t-test
Statistical analysis description: T-test performed in each group	
Comparison groups	Group A v Group B v Group C v Group D v Group E v Group F v Group G v Group H
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.01 ^[1]
Method	Fisher exact

Notes:

[1] - Group A: p=0.01

Group B: p=0.8

Group C: p=0.08

Group D: p=0.005

Group E: p=0.02

Group F: p=0.28

Group G: p=0.46

Group H: o=0.02

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From inclusion to participant was terminated from the trial one week after the last visit.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25
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Reporting groups

Reporting group title	All participants
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Reporting group description: -

Serious adverse events	All participants		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 92 (1.09%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Nervous system disorders			
Apoplectic stroke			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	All participants		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 92 (41.30%)		
Nervous system disorders			
Periodic headache			
subjects affected / exposed	23 / 92 (25.00%)		
occurrences (all)	23		
Gastrointestinal disorders			
nausea/vomiting			
subjects affected / exposed	13 / 92 (14.13%)		
occurrences (all)	13		
Loose stools			

subjects affected / exposed	9 / 92 (9.78%)		
occurrences (all)	9		

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
01 May 2023	Sodium chloride tablets out of stock.	01 November 2023

Notes:

Limitations and caveats

None reported