Clinical trial results:
Zoledronic acid for prevention of bone loss after bariatric surgery

Summary

EudraCT number	2019-001650-26
Trial protocol	DK
Global end of trial date	30 October 2024

Results information

Result version number	v1 (current)
This version publication date	28 December 2025
First version publication date	28 December 2025
Summary attachment (see zip file)	Primary outcome (Obesity - 2025 - Gam - Zoledronic acid increases spine bone mass and prevents hip bone loss after bariatric surgery a.pdf) Secondary outcome (Obesity - 2025 - Gam - Effect of Zoledronic Acid on Skeletal Muscle After Bariatric Surgery A Secondary Analysis From a.pdf) Summery (ZABAS Trial – Summary of Results (EudraCT 2019-001650-26).pdf)

Trial information

Trial identification

Sponsor protocol code	ZOL6700

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04742010
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hospital South West Jutland
Sponsor organisation address	Finsensgade 35, Esbjerg, Denmark, 6700
Public contact	Department of Medicine, Hospital South West Jutland, 0045 79182226, stinus.gadegaard.hansen@rsyd.dk
Scientific contact	Department of Medicine, Hospital South West Jutland, 0045 79182226, soren.gam@rsyd.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 February 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 October 2024
Global end of trial reached?	Yes
Global end of trial date	30 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effects of zoledronic acid on bone mineral density in patients after bariatric surgery.,

Protection of trial subjects:

All participants provided written informed consent prior to inclusion. The study was approved by the Regional Committees on Health Research Ethics for Southern Denmark (project identifier S-20190134) and by the Danish Medicines Agency (protocol ZOL6700). The trial followed the Declaration of Helsinki and Good Clinical Practice requirements. Safety was monitored throughout the study period, and all serious adverse events were reported to the relevant Danish authorities and monitored by the local GCP-unit. Women of childbearing potential used approved contraception and were screened for pregnancy prior to study drug infusion

Background therapy:

All participants received standard postoperative care for bariatric surgery including routine supplementation with calcium and vitamin D in accordance with Danish national guidelines. In case of vitamin D deficiency, a standard loading regimen was provided. No other anti-osteoporotic treatment was allowed.

Evidence for comparator:

Zoledronic acid is an approved bisphosphonate widely used for prevention of bone loss and fractures in osteoporosis. Placebo was chosen as comparator because the effect of zoledronic acid in patients undergoing bariatric surgery is unknown and no pharmacological standard of care exists in this population. A placebo-controlled design is therefore necessary to evaluate treatment effects on bone and muscle outcomes in this setting

Actual start date of recruitment	11 February 2021
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: 59
Worldwide total number of subjects	59
EEA total number of subjects	59

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)	59
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited consecutively from the bariatric surgery program at the University Hospital of Southern Denmark, Esbjerg. Eligible patients were invited during standard preoperative assessments, and written informed consent was obtained prior to any study procedures.

Pre-assignment

Screening details:

Potential participants were screened for eligibility based on predefined inclusion and exclusion criteria, including indication for bariatric surgery, age ≥35 years, obesity-related comorbidities, and absence of contraindications to zoledronic acid. Screening included medical history, laboratory values, and verification of vitamin D status. Women o

Period 1

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

Blinding implementation details:

Participants, investigators and outcome assessors were blinded throughout data collection. Randomization was computer-generated with stratification and concealed allocation. A non-study team member prepared the unblinded report. The main analyst (SG) remained blinded during statistical analyses and was only unblinded after analyses were completed.

Arms

Are arms mutually exclusive?	Yes
Arm title	Intervention

Arm description:

Participants received a single intravenous infusion of zoledronic acid 5 mg prior to bariatric surgery in addition to standard postoperative supplementation.

Arm type	Experimental
Investigational medicinal product name	Zoledronic acid
Investigational medicinal product code	49015
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects will receive a single dose of zoledronic acid 5 mg or placebo 21 days before bariatric surgery (an interval of 59 to 7 days is accepted). Zoledronic acid or placebo will be administered in a solution containing 100-ml normal saline and slowly infused intravenous (≥15 min). Due to the risk of anaphylaxis, subjects are observed at least 30 min on the study site after the infusion. The Pharmacy, University hospital of Southern Denmark, will prepare the study medicine on the day of administration. Preparation is performed at a separate location in the hospital away from the research facility. Zoledronic acid or placebo solutions will be identical and labeled only with the randomization number of the particular subject.

Arm title	Placebo

Arm description:

Participants received a single intravenous infusion of placebo (0.9% NaCl) prior to bariatric surgery in addition to standard postoperative supplementation.

Arm type	Placebo

Investigational medicinal product name	Saline water
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

a solution containing 100 mL of saline water (0.9% sodium chloride)and slowly infused intravenously (≥15 min).

Number of subjects in period 1	Intervention	Placebo
Started	31	28
Completed	31	28

Baseline characteristics

Reporting groups	
Reporting group title	Recriument and randomization

Reporting group description: -

Reporting group values	Recriument and randomization	Total	
Number of subjects	59	59	
Age categorical Units: Subjects			
Age continuous			
48.9 yr. +/- 6.3 SD			
Units: years median standard deviation	 48.9 ± 6.3	 -	
Gender categorical Units: Subjects			
Male Female	16 43	16 43	
Spine vBMD Units: mg/cm3 arithmetic mean standard deviation	 147.9 ± 29.2	 -	
Hip vBMD Units: mg/cm3 arithmetic mean standard deviation	 163.6 ± 16.9	 -	
Bone turnover markers - CTX-1 Units: µg/L arithmetic mean standard deviation	 0.26 ± 0.16	 -	

End points

End points reporting groups

Reporting group title	Intervention

Reporting group description:

Participants received a single intravenous infusion of zoledronic acid 5 mg prior to bariatric surgery in addition to standard postoperative supplementation.

Reporting group title	Placebo

Reporting group description:

Participants received a single intravenous infusion of placebo (0.9% NaCl) prior to bariatric surgery in addition to standard postoperative supplementation.

Subject analysis set title	Analysis of primary outcome
Subject analysis set type	Intention-to-treat

Subject analysis set description:

The intentiontotreat principle was used to analyze the effect of zoledronic acid. A mixedeffects model with repeated measures, including a term for the interaction of group (INT or CON) and time, was used to assess changes from baseline to 12months (unadjusted analysis). For the adjusted analysis, the covariates age, gender, and surgery type (randomization factor) were included in the analysis

Primary: Spine vBMD

End point title	Spine vBMD

End point description:

End point type	Primary

End point timeframe:

Baseline to 1 year

End point values	Intervention	Placebo	Analysis of primary outcome	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	31	28		
Units: mg/cm3				
arithmetic mean (confidence interval 95%)	153.1 (144.2 to 162.1)	140.4 (133.9 to 158.2)	6.8 (1.9 to 11.7)	

Attachments (see zip file)	Obesity - 2025 - Gam - Zoledronic acid increases spine bone

Statistical analyses

Statistical analysis title	Analysis plan for all main outcomes

Statistical analysis description:

The intentiontotreat principle was used to analyze the effect of zoledronic acid. A mixedeffects model with repeated measures, including a term for the interaction of group (INT or CON) and time, was used to assess changes from baseline to 12months (unadjusted analysis). For the adjusted analysis, the covariates age, gender, and surgery type (randomization factor) were included in the analysis.

Comparison groups	Intervention v Placebo

Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	< 0.05
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	6.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.9
upper limit	11.7
Variability estimate	Standard deviation
Dispersion value	0.05

Notes:

[1] - The intentiontotreat principle was used to analyze the effect of zoledronic acid. A mixed effects model with repeated measures, including a term for the interaction of group (INT or CON) and time, was used to assess changes from baseline to 12months (unadjusted analysis). For the adjusted analysis, the covariates age, gender, and surgery type (randomization factor) were included in the analysis.

Secondary: Hip vBMD

End point title	Hip vBMD

End point description:

End point type	Secondary

End point timeframe:

Baseline to 1 year post

End point values	Intervention	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	28		
Units: mg/cm3				
arithmetic mean (confidence interval 95%)	162.0 (156.6 to 167.4)	156.7 (150.9 to 162.5)		

Attachments (see zip file)	see table 2/Obesity - 2025 - Gam - Zoledronic acid increases

Statistical analyses

Statistical analysis title	Analysis plan for all main outcomes

Statistical analysis description:

The intentiontotreat principle was used to analyze the effect of zoledronic acid. A mixedeffects model with repeated measures, including a term for the interaction of group (INT or CON) and time, was used to assess changes from baseline to 12months (unadjusted analysis). For the adjusted analysis, the covariates age, gender, and surgery type (randomization factor) were included in the analysis

Comparison groups	Intervention v Placebo

Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	8.5
Variability estimate	Standard deviation
Dispersion value	0.05

Statistical analysis title	Copy of Analysis plan for all main outcomes

Statistical analysis description:

The intentiontotreat principle was used to analyze the effect of zoledronic acid. A mixedeffects model with repeated measures, including a term for the interaction of group (INT or CON) and time, was used to assess changes from baseline to 12months (unadjusted analysis). For the adjusted analysis, the covariates age, gender, and surgery type (randomization factor) were included in the analysis

Comparison groups	Intervention v Placebo
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	8.5
Variability estimate	Standard deviation
Dispersion value	0.05

Secondary: Bone markers - CTX-1

End point title	Bone markers - CTX-1

End point description:

End point type	Secondary

End point timeframe:

Baseline to 1 years

End point values	Intervention	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	28		
Units: µg/L				
arithmetic mean (confidence interval 95%)	0.53 (0.45 to 0.61)	0.71 (0.62 to 0.80)		

Statistical analyses

Statistical analysis title	Analysis plan for all main outcomes
Comparison groups	Intervention v Placebo
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	-0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.32
upper limit	-0.04
Variability estimate	Standard deviation
Dispersion value	0.05

Adverse events

Adverse events information

Timeframe for reporting adverse events:

baseline to 1 year follow up

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25

Reporting groups

Reporting group title	Intervention

Reporting group description:

Participants received a single intravenous infusion of zoledronic acid 5 mg prior to bariatric surgery in addition to standard postoperative supplementation.

Reporting group title	Placebo

Reporting group description:

Participants received a single intravenous infusion of placebo (0.9% NaCl) prior to bariatric surgery in addition to standard postoperative supplementation.

Serious adverse events	Intervention	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 31 (25.81%)	4 / 28 (14.29%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
Chest pain	Additional description: Chest pain without clinically significant findings.		
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Hospitalisation	Additional description: Two-day prolongation of hospital stay after bariatric surgery.		
subjects affected / exposed	0 / 31 (0.00%)	1 / 28 (3.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haematoma	Additional description: Abdominal wall haematoma.		
subjects affected / exposed	0 / 31 (0.00%)	2 / 28 (7.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain	Additional description: Abdominal pain five days after RYGB, attributed to		

	oedema at the anastomosis.		
subjects affected / exposed	2 / 31 (6.45%)	1 / 28 (3.57%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic due to gallstones.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hospitalisation and surgery for ileus with adhesiolysis.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hospitalisation due to abdominal pain			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea and vomiting, attributed to protein drinks without suspicion of RYGB-related complications.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hospitalisation due to incarcerated incisional hernia	Additional description: Hospitalisation due to incarcerated incisional hernia.		
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Viral upper respiratory tract infection.			

subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (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	Intervention	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 31 (83.87%)	19 / 28 (67.86%)	
Cardiac disorders			
Vasovagal episode			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Arterial hypertension			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
Gastroenteritis.			
subjects affected / exposed	0 / 31 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Elective ERCP with removal of stone from the common bile duct.			
subjects affected / exposed	0 / 31 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Abdominal pain.			
subjects affected / exposed	0 / 31 (0.00%)	2 / 28 (7.14%)	
occurrences (all)	0	2	
Anastomotic ulcer at the gastrojejunal anastomosis.			
subjects affected / exposed	0 / 31 (0.00%)	2 / 28 (7.14%)	
occurrences (all)	0	2	
Nephrolithiasis identified on CT scan.			
subjects affected / exposed	1 / 31 (3.23%)	1 / 28 (3.57%)	
occurrences (all)	1	1	
Hiatus hernia.			

subjects affected / exposed	0 / 31 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Stenosis at the upper anastomosis.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Postprandial hypoglycaemia after RYGB.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Vitamin D insufficiency.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Hypocalcaemia	Additional description: Hypocalcaemia (total calcium 2.13 mmol/L, corrected 2.18 mmol/L).		
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Fall 2 with wound on tibia and subsequent infection; treated with roxithromycin; delayed			
subjects affected / exposed	2 / 31 (6.45%)	0 / 28 (0.00%)	
occurrences (all)	2	0	
Basal cell carcinoma of the scalp, excised.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Removal of benign skin tumour on the nose.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Haematoma after subcutaneous administration of study medication.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Stafylokok infektion with wound in the skin			
subjects affected / exposed	0 / 31 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Renal and urinary disorders			

Benign prostatic hyperplasia.			
subjects affected / exposed	0 / 31 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Urinary tract infection.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Elective surgery			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Flank pain and haematuria.			
subjects affected / exposed	0 / 31 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Transient elevation of serum creatinine (101 µmol/L), normalised on repeat testing.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Menorrhagia; evaluated by gynaecologist without significant abnormalities; treated with intrauterine			
subjects affected / exposed	0 / 31 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Renal cyst.			
subjects affected / exposed	0 / 31 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Ureterolithiasis with hydronephrosis	Additional description: Ureterolithiasis with hydronephrosis; treatment with stone extraction and JJ stent placement and exchange.		
subjects affected / exposed	0 / 31 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Knee osteoarthritis with increased pain and reduced walking distance.			
subjects affected / exposed	0 / 31 (0.00%)	2 / 28 (7.14%)	
occurrences (all)	0	2	
Gout with pain in the right knee and great toe	Additional description: Gout with pain in the right knee and great toe; treated with Dolol and Seractiv.		
subjects affected / exposed	1 / 31 (3.23%)	1 / 28 (3.57%)	
occurrences (all)	1	1	
Fall from bicycle with shoulder	Additional description: Fall from bicycle with shoulder contusion; no medical		

contusion	consultation sought.		
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Broken RIB			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Fall with contusion of the shoulder.			
subjects affected / exposed	1 / 31 (3.23%)	1 / 28 (3.57%)	
occurrences (all)	1	1	
Fatigue, muscle tension and nocturnal restlessness in the legs.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Joint swelling of knee and elbow.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	
Myalgia of the upper extremities.			
subjects affected / exposed	0 / 31 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Pain in both knees after bariatric surgery.			
subjects affected / exposed	0 / 31 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Pain in hip and back.			
subjects affected / exposed	1 / 31 (3.23%)	1 / 28 (3.57%)	
occurrences (all)	1	1	
Phalanx fracture of the left third finger.			
subjects affected / exposed	0 / 31 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
Shoulder pain with tendinopathy and bursitis.			
subjects affected / exposed	1 / 31 (3.23%)	1 / 28 (3.57%)	
occurrences (all)	1	1	
Infections and infestations			
Helicobacter pylori infection diagnosed by breath test.			

subjects affected / exposed	0 / 31 (0.00%)	1 / 28 (3.57%)	
occurrences (all)	0	1	
COVID infektion			
subjects affected / exposed	10 / 31 (32.26%)	4 / 28 (14.29%)	
occurrences (all)	12	4	
Influenza-like symptoms after study medication.			
subjects affected / exposed	15 / 31 (48.39%)	6 / 28 (21.43%)	
occurrences (all)	15	6	
Hemolytic streptococcal infection treated with penicillin.			
subjects affected / exposed	1 / 31 (3.23%)	0 / 28 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 November 2020	Reduction of study duration The total trial period was reduced from 36 months to 24 months. This amendment was made following slower-than-expected recruitment during the initial phase of the study and alignment with the revised timeline for follow-up assessments. Introduction of IPAQ questionnaire The International Physical Activity Questionnaire (IPAQ) was added to the data collection battery in order to capture self-reported physical activity levels throughout follow-up, complementing objective strength and physical function assessment Adjustment of sample size The planned number of participants was revised from 70 to 50. The revised sample size was considered sufficient to address the primary objective while taking into account enrollment feasibility and available study resources.
18 December 2023	Adjustment of sample size The planned number of participants was revised from 50 to 60. The revised sample size was considered sufficient to address the primary objective while taking into account enrollment feasibility and available study resources.

Notes:

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/36209245

http://www.ncbi.nlm.nih.gov/pubmed/39978415

http://www.ncbi.nlm.nih.gov/pubmed/4117714