Clinical trial results:
Effect of the administration of different Hidroferol® Soft Gelatine Capsules (calcifediol) and cholecalciferol (Dibase®) regimens on 25(OH) D levels and markers of bone remodelling in postmenopausal women with 25(OH)D deficiency.
Influence of clinical and genetic factors in the osteoporotic and non-osteoporotic population.

Summary

EudraCT number	2017-004028-31
Trial protocol	ES IT
Global end of trial date	11 August 2020

Results information

Result version number	v1 (current)
This version publication date	15 February 2025
First version publication date	15 February 2025

Trial information

Trial identification

Sponsor protocol code	HIDR-0217/OST

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	FAES FARMA, S.A.
Sponsor organisation address	Avenida Autonomía 10, Leioa, Spain, 48940
Public contact	Inmaculada Gilaberte, FAES FARMA, S.A., 0034 94 481 83 00, igilaberte@faes.es
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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	24 March 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 August 2020
Global end of trial reached?	Yes
Global end of trial date	11 August 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy and safety in postmenopausal women with vitamin D deficiency, with or without osteoporosis, of the long-term treatment with Hidroferol® Soft Gelatine Capsules (SGC) in the correction and maintenance of normal values of vitamin D comparing with the approved regimen and with the treatment recommended by the current European Guidance .

Protection of trial subjects:

The study is conducted in accordance with the Declaration of Helsinki (2013) as well as with the valid national laws of the participating countries, with the International Conference on Harmonisation (ICH) Harmonised Tripartite Guideline for Good Clinical Practice (GCP) (E6), and with the Commission Directives 2001/20/EC, 2005/28/EC and 2001/83/EC.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 2017
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	Spain: 289
Country: Number of subjects enrolled	Italy: 14
Worldwide total number of subjects	303
EEA total number of subjects	303

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)	187
From 65 to 84 years	113

85 years and over	3

Subject disposition

Recruitment

Recruitment details:

A total of 401 subjects were enrolled at 13 study sites in 2 countries (Spain and Italy). Of these, 98 subjects failed screening. In total 303 subjects of both cohorts (Cohort1: 270 subjects, Cohort2: 33 subjects) were randomised.

Pre-assignment

Screening details:

98 subjects failed screening. In total 303 subjects of both cohorts (Cohort1: 270 subjects, Cohort2: 33 subjects) were randomised by 11 AUG 2020.

Period 1

Period 1 title	Randomization
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	Group A1

Arm description:

Hidroferol® experimental treatment

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

Dosage and administration details:

group A1 (test group, 102 patients). Hidroferol® experimental treatment. Patients received:
o 1 soft gelatin capsule of calcifediol (0.266 mg) once a month for 12 months, plus
o 1 jar (single dose container) of 2.5 mL of placebo oral solution once a month for 12 months.

Arm title	Group A2

Arm description:

Hidroferol® treatment according to approved SmPC posology

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

Dosage and administration details:

• group A2 (SmPC group, 101 patients). Hidroferol® treatment according to approved SmPC posology. Patients received:
o 1 soft gelatin capsule of calcifediol (0.266 mg) once a month for 4 months.
o 1 soft gelatin capsule of placebo once a month from Month 5 to Month 12.
o 1 jar (single dose container) of 2.5 mL of placebo oral solution once a month for 12 months.

Arm title	Group B

Arm description:

Cholecalciferol (Dibase®) as recommended by therapeutic guidelines

Arm type	Experimental
Investigational medicinal product name	Cholecalciferol (Dibase)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution in bottle
Routes of administration	Oral use

Dosage and administration details:

• group B (reference group, 100 patients). Cholecalciferol (Dibase®) as recommended by therapeutic guidelines. Patients received:
o 1 jar (single dose container) of 2.5 mL of cholecalciferol (25,000 IU) once a month for 12 months.
o 1 soft gelatin capsule of placebo once a month for 12 months.

Number of subjects in period 1	Group A1	Group A2	Group B
Started	102	101	100
Completed	102	101	100

Period 2

Period 2 title	Period 1: 0-4 months
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Data analyst, Carer, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Group A1

Arm description:

Hidroferol® experimental treatment.

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

Dosage and administration details:

group A1 (test group, 102 patients). Hidroferol® experimental treatment. Patients received:
o 1 soft gelatin capsule of calcifediol (0.266 mg) once a month for 12 months, plus
o 1 jar (single dose container) of 2.5 mL of placebo oral solution once a month for 12 months.

Arm title	Group A2

Arm description:

Hidroferol® treatment according to approved SmPC posology

Arm type	Experimental

Investigational medicinal product name	Hidroferol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

• group A2 (SmPC group, 101 patients). Hidroferol® treatment according to approved SmPC posology. Patients received:
o 1 soft gelatin capsule of calcifediol (0.266 mg) once a month for 4 months.
o 1 soft gelatin capsule of placebo once a month from Month 5 to Month 12.
o 1 jar (single dose container) of 2.5 mL of placebo oral solution once a month for 12 months.

Arm title	Group B

Arm description:

Cholecalciferol (Dibase®) as recommended by therapeutic guidelines.

Arm type	Experimental
Investigational medicinal product name	Cholecalciferol (Dibase)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution in bottle
Routes of administration	Oral use

Dosage and administration details:

• group B (reference group, 100 patients). Cholecalciferol (Dibase®) as recommended by therapeutic guidelines. Patients received:
o 1 jar (single dose container) of 2.5 mL of cholecalciferol (25,000 IU) once a month for 12 months.
o 1 soft gelatin capsule of placebo once a month for 12 months.

Number of subjects in period 2	Group A1	Group A2	Group B
Started	102	101	100
Completed	99	96	96
Not completed	3	5	4
Consent withdrawn by subject	-	5	2
Adverse event, non-fatal	-	-	1
Protocol deviation	3	-	1

Period 3

Period 3 title	Period 2: 4-12 months
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Subject, Data analyst, Carer

Arms

Are arms mutually exclusive?	Yes

Arm title	Group A1

Arm description:

Hidroferol® experimental treatment.

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

Dosage and administration details:

group A1 (test group, 102 patients). Hidroferol® experimental treatment. Patients received:
o 1 soft gelatin capsule of calcifediol (0.266 mg) once a month for 12 months, plus
o 1 jar (single dose container) of 2.5 mL of placebo oral solution once a month for 12 months.

Arm title	Group A2

Arm description:

Hidroferol® treatment according to approved SmPC posology.

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

Dosage and administration details:

• group A2 (SmPC group, 101 patients). Hidroferol® treatment according to approved SmPC posology. Patients received:
o 1 soft gelatin capsule of calcifediol (0.266 mg) once a month for 4 months.
o 1 soft gelatin capsule of placebo once a month from Month 5 to Month 12.
o 1 jar (single dose container) of 2.5 mL of placebo oral solution once a month for 12 months.

Arm title	Group B

Arm description:

Cholecalciferol (Dibase®) as recommended by therapeutic guidelines

Arm type	Experimental
Investigational medicinal product name	Cholecalciferol (Dibase)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution in bottle
Routes of administration	Oral use

Dosage and administration details:

• group B (reference group, 100 patients). Cholecalciferol (Dibase®) as recommended by therapeutic guidelines. Patients received:
o 1 jar (single dose container) of 2.5 mL of cholecalciferol (25,000 IU) once a month for 12 months.
o 1 soft gelatin capsule of placebo once a month for 12 months.

Number of subjects in period 3	Group A1	Group A2	Group B
Started	99	96	96
Completed	95	75	88
Not completed	4	21	8
Consent withdrawn by subject	-	2	3
Serum 25(OH)D<10ng/mL	-	14	-
COVID Pandemic	-	-	1
Adverse event, non-fatal	1	-	1
Low adherence	1	1	1
Lost to follow-up	-	2	-
Protocol deviation	2	2	2

Period 4	
Period 4 title	Safety Follow-up
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	Group A1

Arm description: -

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

Dosage and administration details:

group A1 (test group, 102 patients). Hidroferol® experimental treatment. Patients received:
o 1 soft gelatin capsule of calcifediol (0.266 mg) once a month for 12 months, plus
o 1 jar (single dose container) of 2.5 mL of placebo oral solution once a month for 12 months.

Arm title	Group A2

Arm description: -

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

Dosage and administration details:

• group A2 (SmPC group, 101 patients). Hidroferol® treatment according to approved SmPC posology. Patients received:

o 1 soft gelatin capsule of calcifediol (0.266 mg) once a month for 4 months.
o 1 soft gelatin capsule of placebo once a month from Month 5 to Month 12.
o 1 jar (single dose container) of 2.5 mL of placebo oral solution once a month for 12 months.

Arm title	Group B
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Cholecalciferol (Dibase)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution in bottle
Routes of administration	Oral use

Dosage and administration details:

• group B (reference group, 100 patients). Cholecalciferol (Dibase®) as recommended by therapeutic guidelines. Patients received:
o 1 jar (single dose container) of 2.5 mL of cholecalciferol (25,000 IU) once a month for 12 months.
o 1 soft gelatin capsule of placebo once a month for 12 months.

Number of subjects in period 4	Group A1	Group A2	Group B
Started	95	75	88
Completed	95	75	88

Baseline characteristics

Reporting groups	
Reporting group title	Group A1
Reporting group description:	
Hidroferol® experimental treatment	
Reporting group title	Group A2
Reporting group description:	
Hidroferol® treatment according to approved SmPC posology	
Reporting group title	Group B
Reporting group description:	
Cholecalciferol (Dibase®) as recommended by therapeutic guidelines	

Reporting group values	Group A1	Group A2	Group B
Number of subjects	102	101	100
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)	59	67	61
From 65-84 years	43	33	37
85 years and over	0	1	2
Age continuous Units: years			
arithmetic mean	64.3	62.4	63.9
standard deviation	± 8.2	± 7.6	± 9.2
Gender categorical Units: Subjects			
Female	102	101	100
Male	0	0	0

Reporting group values	Total		
Number of subjects	303		
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)	187		
From 65-84 years	113		
85 years and over	3		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	303		
Male	0		

End points

End points reporting groups

Reporting group title	Group A1
Reporting group description: Hidroferol® experimental treatment	
Reporting group title	Group A2
Reporting group description: Hidroferol® treatment according to approved SmPC posology	
Reporting group title	Group B
Reporting group description: Cholecalciferol (Dibase®) as recommended by therapeutic guidelines	

Reporting group title	Group A1
Reporting group description: Hidroferol® experimental treatment.	
Reporting group title	Group A2
Reporting group description: Hidroferol® treatment according to approved SmPC posology	
Reporting group title	Group B
Reporting group description: Cholecalciferol (Dibase®) as recommended by therapeutic guidelines.	
Reporting group title	Group A1
Reporting group description: Hidroferol® experimental treatment.	
Reporting group title	Group A2
Reporting group description: Hidroferol® treatment according to approved SmPC posology.	
Reporting group title	Group B
Reporting group description: Cholecalciferol (Dibase®) as recommended by therapeutic guidelines	
Reporting group title	Group A1
Reporting group description: -	
Reporting group title	Group A2
Reporting group description: -	
Reporting group title	Group B
Reporting group description: -	

Primary: Primary efficacy endpoint

End point title	Primary efficacy endpoint
End point description: The primary efficacy endpoint was the percentage of patients achieving 25(OH)D levels >30 ng/mL at month 4, for each treatment group	
End point type	Primary
End point timeframe: Month 4	

End point values	Group A1	Group A2	Group B	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	85[1]	77[2]	78[3]	
Units: ng/mL				
number (confidence interval 95%)	29.4 (20.0 to 40.3)	37.7 (26.9 to 49.4)	5.1 (1.4 to 12.6)	

Notes:

[1] - Main efficacy endpoint performed in Per Protocol population

[2] - Main efficacy endpoint performed in Per Protocol population

[3] - Main efficacy endpoint performed in Per Protocol population

Statistical analyses

Statistical analysis title	chi-square test
Comparison groups	Group A1 v Group A2 v Group B
Number of subjects included in analysis	240
Analysis specification	Pre-specified
Analysis type	superiority[4]
P-value	< 0.0001
Method	Chi-squared
Confidence interval	
level	95 %

Notes:

[4] - The primary efficacy analysis was to evaluate the superiority of the group A (A.1+A.2) versus group B, based on the percentage of patients achieving 25(OH)D levels above 30 ng/mL at month 4. The comparison was performed using the chi-square test (without continuity correction) and the corresponding 95% asymptotic (Wald) CI for the proportion difference.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The investigator must report all directly observed and all spontaneously reported untoward events (n-TEAEs/TEAEs) from the time informed consent is obtained through patients last study visit.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	Group A1
Reporting group description: -	
Reporting group title	Group A2
Reporting group description: -	
Reporting group title	Group B
Reporting group description: -	

Serious adverse events	Group A1	Group A2	Group B
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 102 (7.84%)	4 / 101 (3.96%)	5 / 100 (5.00%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast neoplasm			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasmacytoma			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Radius fracture			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Atrioventricular block complete			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Autoimmune haemolytic anaemia			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intestinal obstruction			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Infections and infestations			
Atypical Pneumonia			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysematous pyelonephritis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronavirus infection			

subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Group A1	Group A2	Group B
Total subjects affected by non-serious adverse events			
subjects affected / exposed	45 / 102 (44.12%)	43 / 101 (42.57%)	41 / 100 (41.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast neoplasm			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Monoclonal gammopathy			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Plasmacytoma			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 102 (1.96%)	2 / 101 (1.98%)	0 / 100 (0.00%)
occurrences (all)	2	2	0
Deep vein thrombosis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Essential hypertension			

subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Peripheral venous disease			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Phlebitis superficial			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Vasculitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Surgical and medical procedures			
Facet joint block			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Foot operation			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Inguinal hernia repair			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Knee operation			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Limb operation			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Spinal laminectomy			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Tooth extraction			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0

Urethral operation			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Feeling cold			
subjects affected / exposed	1 / 102 (0.98%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Oedema peripheral			
subjects affected / exposed	2 / 102 (1.96%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Asthenia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Social circumstances			
Dental prosthesis user			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences (all)	0	1	1
Reproductive system and breast disorders			
Cervical polyp			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	1 / 102 (0.98%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Productive cough			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences (all)	0	1	1
Acute respiratory failure			

subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Allergic bronchitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Noninfective bronchitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Adjustment disorder with mixed anxiety and depressed mood			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Investigations			
Differential white blood cell count abnormal			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			

Foot fracture			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences (all)	0	1	1
Anaemia postoperative			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Hand fracture			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Ligament sprain			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Radius fracture			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Rib fracture			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	2 / 102 (1.96%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Angina pectoris			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Atrial flutter			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Atrioventricular block complete			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Sinus tachycardia			

subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 102 (1.96%)	2 / 101 (1.98%)	1 / 100 (1.00%)
occurrences (all)	2	2	1
Dizziness			
subjects affected / exposed	2 / 102 (1.96%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Carotid artery stenosis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Migraine with aura			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Parkinson's disease			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Sciatic nerve neuropathy			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Autoimmune haemolytic anaemia			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
White blood cell disorder			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	1 / 102 (0.98%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences (all)	1	1	1
Tinnitus			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Vertigo positional			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Keratitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 102 (1.96%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences (all)	2	1	1
Dyspepsia			
subjects affected / exposed	0 / 102 (0.00%)	2 / 101 (1.98%)	1 / 100 (1.00%)
occurrences (all)	0	2	1
Haemorrhoids			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences (all)	0	1	1
Intestinal obstruction			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	1	0	1
Abdominal discomfort			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Dry mouth			

subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Intra-abdominal fluid collection			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Cold sweat			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences (all)	0	1	1
Eczema			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Urticaria			

subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	1	0	1
Proteinuria			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Renal artery stenosis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Renal pain			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 102 (0.98%)	3 / 101 (2.97%)	3 / 100 (3.00%)
occurrences (all)	1	3	3
Back pain			
subjects affected / exposed	0 / 102 (0.00%)	4 / 101 (3.96%)	3 / 100 (3.00%)
occurrences (all)	0	4	3
Osteoarthritis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	3 / 100 (3.00%)
occurrences (all)	0	1	3
Pain in extremity			
subjects affected / exposed	3 / 102 (2.94%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	3	0	0
Joint swelling			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences (all)	0	1	1
Musculoskeletal pain			
subjects affected / exposed	1 / 102 (0.98%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Rotator cuff syndrome			

subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	1	0	1
Tenosynovitis stenosans			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	2 / 100 (2.00%)
occurrences (all)	0	0	2
Bone pain			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Bursitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Osteitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Osteopenia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Osteoporosis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Periarthritis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Polymyalgia rheumatica			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 102 (2.94%)	4 / 101 (3.96%)	2 / 100 (2.00%)
occurrences (all)	3	4	2
Gastroenteritis			
subjects affected / exposed	1 / 102 (0.98%)	1 / 101 (0.99%)	3 / 100 (3.00%)
occurrences (all)	1	1	3

Urinary tract infection			
subjects affected / exposed	1 / 102 (0.98%)	1 / 101 (0.99%)	3 / 100 (3.00%)
occurrences (all)	1	1	3
Cystitis			
subjects affected / exposed	0 / 102 (0.00%)	2 / 101 (1.98%)	2 / 100 (2.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 102 (0.98%)	3 / 101 (2.97%)	0 / 100 (0.00%)
occurrences (all)	1	3	0
Otitis externa			
subjects affected / exposed	1 / 102 (0.98%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences (all)	1	1	1
Influenza			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences (all)	0	1	1
Pharyngitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	2 / 100 (2.00%)
occurrences (all)	0	0	2
Pneumonia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences (all)	0	1	1
Adenoviral conjunctivitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Adenoviral upper respiratory infection			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Appendicitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Atypical pneumonia			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Bronchitis bacterial			

subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Chronic sinusitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Coronavirus infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Emphysematous pyelonephritis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Pneumonia viral			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Tinea cruris			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Tracheitis			

subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	1 / 102 (0.98%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Vitamin B12 deficiency			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	1	0	1
Food intolerance			
subjects affected / exposed	0 / 102 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 December 2017	Key modifications covered by protocol V.2.0 were related to the possibility of storing study samples at a biobank (Basque Biobank), the update of contact details of the CRO in charge of study monitoring in Italy and rewording of some paragraphs to better clarify certain sections of the protocol.
30 May 2018	Changes at protocol V.2.1 essentially included an interim analysis when 100% of patients had completed 4 months of study - or had early discontinued prior to this visit. This interim analysis included the planned analysis of primary efficacy endpoint based on the Hidroferol® treatment duration recommended in the currently approved SmPC (i.e. 4 months). Assessment of primary endpoint at month 4 was already included in the statistical plan of previous protocol version V.2.0, but to be analyzed after the end of study, i.e. in the overall study analysis. According to protocol V.2.1, the primary endpoint along with secondary endpoints planned at month 4 were then timely analyzed in an interim analysis before the end of study (refer to the 'Interim Analysis CSR for Primary Endpoint' of the study HIDR- 0217/OST).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported