Clinical trial results:
SAFETY AND PHARMACOKINETICS OF ODM-209 IN PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER OR ESTROGEN RECEPTOR-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2-NEGATIVE ADVANCED BREAST CANCER

Summary

EudraCT number	2018-002249-13
Trial protocol	FI DK ES IT
Global end of trial date	09 January 2024

Results information

Result version number	v1 (current)
This version publication date	29 December 2024
First version publication date	29 December 2024

Trial information

Trial identification

Sponsor protocol code	03125001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03878823
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Orion Corporation Orion Pharma
Sponsor organisation address	Orionintie 1, Espoo, Finland, 02200
Public contact	clinicaltrials@orionpharma.com, Orion Corporation Orion Pharma, 358 0104261, clinicaltrials@orionpharma.com
Scientific contact	clinicaltrials@orionpharma.com, Orion Corporation Orion Pharma, 358 0104261, clinicaltrials@orionpharma.com

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	09 January 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 January 2024
Global end of trial reached?	Yes
Global end of trial date	09 January 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Part 1:
Primary objectives are
- to evaluate the safety and tolerability of ODM-209;
- to define the maximum tolerated dose (MTD) and dose limiting toxicities (DLTs) of ODM-209, if feasible;
- to define the recommended dose of ODM-209 for prostate cancer and breast cancer patients and replacement therapy for Part 2 of the study.

Part 2:
- to further evaluate the safety and tolerability of ODM-209;
- to evaluate the preliminary anticancer activity of ODM-209.

Protection of trial subjects:

Dosing of ODM-209 was started with low dose in cohort 1 and gradually increased based on tolerability results evaluated by sponsor and the independent safety monitoring board (SMB).
Safety was assessed by AEs, laboratory tests, physical examination, vital signs including orthostatic test and 12-lead ECG.
Concomitant glucocorticoid and mineralocorticoids replacement therapy was given to subjects to decrease the risk of developing adrenal insufficiency.
Criteria for ODM-209 and replacement therapy dosing interruption and modifications were described in the protocol.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 April 2019
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: 10
Country: Number of subjects enrolled	Finland: 7
Country: Number of subjects enrolled	France: 21
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)	14
From 65 to 84 years	24
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 38 subjects with with metastatic castration-resistant prostate cancer or estrogen receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer were enrolled in the study at 4 study centers in Europe during the years 2019-2024.

Pre-assignment

Screening details:

Male or female aged ≥ 18 years with histologically confirmed carcinoma and adequate marrow, liver, and kidney function were recruited. All of the inclusion criteria and none of the exclusion criteria fulfilled, and written informed consent given. In total, 53 subjects were screened and 38 participants enrolled and started the treatment.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not applicable

Arms

Are arms mutually exclusive?	Yes
Arm title	ODM-209 10 mg

Arm description: -

Arm type	Experimental
Investigational medicinal product name	ODM-209 10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

The daily dose of 10 mg ODM-209 was taken with a glass of water within 30 min after a meal.

Arm title	ODM-209 15 mg

Arm description: -

Arm type	Experimental
Investigational medicinal product name	ODM-209 15 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

The daily dose of 15 mg ODM-209 was taken with a glass of water within 30 min after a meal.

Arm title	ODM-209 20 mg

Arm description: -

Arm type	Experimental

Investigational medicinal product name	ODM-209 20 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

The daily dose of 20 mg ODM-209 was taken with a glass of water within 30 min after a meal.

Number of subjects in period 1	ODM-209 10 mg	ODM-209 15 mg	ODM-209 20 mg
Started	13	6	19
Completed	13	6	19

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	38	38	
Age categorical Units: Subjects			
Adults (18-64 years)	14	14	
From 65-84 years	24	24	
Gender categorical Units: Subjects			
Female	4	4	
Male	34	34	

End points

End points reporting groups

Reporting group title	ODM-209 10 mg
Reporting group description: -	
Reporting group title	ODM-209 15 mg
Reporting group description: -	
Reporting group title	ODM-209 20 mg
Reporting group description: -	

Primary: Frequency of adverse events

End point title	Frequency of adverse events[1]
End point description:	
Number of subjects with treatment related adverse events.	
End point type	Primary
End point timeframe:	
From the first dose of ODM-209 until the end of study visit.	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Frequency of adverse events was described by descriptive statistics. No clear difference in the overall frequency of AEs was seen between the different doses (10, 15 and 20 mg).

End point values	ODM-209 10 mg	ODM-209 15 mg	ODM-209 20 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	6	19	
Units: Adverse events	7	4	15	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the first dose of ODM-209 until the last visit.

Adverse event reporting additional description:

No clear difference in the overall frequency of AEs was seen between the different doses (10, 15 and 20 mg). Grade ≥3 AEs were more frequently reported in 10 mg and 15 mg groups compared to 20 mg group. The adverse events reported were for the most part anticipated based on the therapeutic mechanism of action of ODM-209 and the patient population.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	ODM-209 10 mg
Reporting group description: -	
Reporting group title	ODM-209 20 mg
Reporting group description: -	
Reporting group title	ODM-209 15 mg
Reporting group description: -	

Serious adverse events	ODM-209 10 mg	ODM-209 20 mg	ODM-209 15 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 13 (38.46%)	8 / 19 (42.11%)	3 / 6 (50.00%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (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
METASTASES TO MENINGES			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (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
PROSTATE CANCER			
subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vascular disorders			
HYPOTENSION			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CEREBELLAR INFARCTION			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (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
SPINAL CORD COMPRESSION			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (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
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GAIT DISTURBANCE			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (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
Hepatobiliary disorders			
HEPATITIS			

subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
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			
DYSPNOEA			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (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
PULMONARY EMBOLISM			
subjects affected / exposed	2 / 13 (15.38%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (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
Renal and urinary disorders			
HYDRONEPHROSIS			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (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
RENAL FAILURE			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (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
URINARY RETENTION			
subjects affected / exposed	2 / 13 (15.38%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

URINARY INCONTINENCE			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (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
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (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
Endocrine disorders			
ADRENOCORTICAL INSUFFICIENCY ACUTE			
subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADRENAL INSUFFICIENCY			
subjects affected / exposed	1 / 13 (7.69%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (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
Infections and infestations			
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (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
SKIN INFECTION			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			

subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (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
STAPHYLOCOCCAL SEPSIS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBMANDIBULAR ABSCESS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (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

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

Non-serious adverse events	ODM-209 10 mg	ODM-209 20 mg	ODM-209 15 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 13 (100.00%)	19 / 19 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR PAIN			
subjects affected / exposed	1 / 13 (7.69%)	3 / 19 (15.79%)	2 / 6 (33.33%)
occurrences (all)	1	3	2
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
HAEMATOMA			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
HOT FLUSH			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2
HYPERTENSION			
subjects affected / exposed	2 / 13 (15.38%)	1 / 19 (5.26%)	2 / 6 (33.33%)
occurrences (all)	2	1	2
HYPOTENSION			

subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	1 / 13 (7.69%)	2 / 19 (10.53%)	1 / 6 (16.67%)
occurrences (all)	1	4	1
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
CHILLS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
FACE OEDEMA			
subjects affected / exposed	2 / 13 (15.38%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
FATIGUE			
subjects affected / exposed	6 / 13 (46.15%)	10 / 19 (52.63%)	4 / 6 (66.67%)
occurrences (all)	7	11	4
GAIT DISTURBANCE			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
MALAISE			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
LOCALISED OEDEMA			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	3 / 13 (23.08%)	7 / 19 (36.84%)	3 / 6 (50.00%)
occurrences (all)	4	11	4
PAIN			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PYREXIA			

subjects affected / exposed	1 / 13 (7.69%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Reproductive system and breast disorders			
ERECTILE DYSFUNCTION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
PELVIC PAIN			
subjects affected / exposed	1 / 13 (7.69%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Respiratory, thoracic and mediastinal disorders			
EPISTAXIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
DYSPNOEA			
subjects affected / exposed	3 / 13 (23.08%)	4 / 19 (21.05%)	1 / 6 (16.67%)
occurrences (all)	4	5	1
COUGH			
subjects affected / exposed	3 / 13 (23.08%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	3	3	0
PLEURAL EFFUSION			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 13 (0.00%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
AGITATION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
ANXIETY			
subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
DEPRESSION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
MANIA			

subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
INSOMNIA			
subjects affected / exposed	3 / 13 (23.08%)	1 / 19 (5.26%)	1 / 6 (16.67%)
occurrences (all)	3	1	1
RESTLESSNESS			
subjects affected / exposed	2 / 13 (15.38%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Investigations			
AMYLASE INCREASED			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 13 (7.69%)	4 / 19 (21.05%)	1 / 6 (16.67%)
occurrences (all)	1	5	1
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	2 / 13 (15.38%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	1 / 13 (7.69%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 13 (7.69%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	2	2	0
BLOOD THYROID STIMULATING HORMONE INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
BLOOD UREA INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 13 (7.69%)	1 / 19 (5.26%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
BLOOD ALKALINE PHOSPHATASE INCREASED			

subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	3 / 19 (15.79%)	1 / 6 (16.67%)
occurrences (all)	0	4	1
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
HAEMOGLOBIN DECREASED			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
SARS-COV-2 TEST POSITIVE			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
WEIGHT INCREASED			
subjects affected / exposed	3 / 13 (23.08%)	7 / 19 (36.84%)	2 / 6 (33.33%)
occurrences (all)	3	7	2
Injury, poisoning and procedural complications			
ARTHROPOD BITE			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
VIITH NERVE INJURY			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			

BRADYCARDIA			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
PALPITATIONS			
subjects affected / exposed	2 / 13 (15.38%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
SINUS BRADYCARDIA			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
SUPRAVENTRICULAR EXTRASYSTOLES			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
AXONAL NEUROPATHY			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
DIZZINESS			
subjects affected / exposed	2 / 13 (15.38%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
DYSGEUSIA			
subjects affected / exposed	0 / 13 (0.00%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
HEADACHE			
subjects affected / exposed	2 / 13 (15.38%)	2 / 19 (10.53%)	1 / 6 (16.67%)
occurrences (all)	2	3	1
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PARAESTHESIA			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
RADICULAR PAIN			
subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
SCIATICA			

subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
SENSORY LOSS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
SYNCOPE			
subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
TASTE DISORDER			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
TREMOR			
subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	2 / 13 (15.38%)	4 / 19 (21.05%)	2 / 6 (33.33%)
occurrences (all)	2	5	3
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
CONJUNCTIVAL HAEMORRHAGE			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
CATARACT			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
EYELID OEDEMA			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
subjects affected / exposed	2 / 13 (15.38%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
ABDOMINAL PAIN			

subjects affected / exposed	0 / 13 (0.00%)	2 / 19 (10.53%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
CONSTIPATION			
subjects affected / exposed	3 / 13 (23.08%)	5 / 19 (26.32%)	1 / 6 (16.67%)
occurrences (all)	3	5	1
DIARRHOEA			
subjects affected / exposed	2 / 13 (15.38%)	2 / 19 (10.53%)	1 / 6 (16.67%)
occurrences (all)	2	3	1
DRY MOUTH			
subjects affected / exposed	1 / 13 (7.69%)	4 / 19 (21.05%)	1 / 6 (16.67%)
occurrences (all)	1	5	1
DYSPEPSIA			
subjects affected / exposed	1 / 13 (7.69%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	1	4	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
NAUSEA			
subjects affected / exposed	2 / 13 (15.38%)	2 / 19 (10.53%)	2 / 6 (33.33%)
occurrences (all)	2	3	2
OESOPHAGITIS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
VOMITING			
subjects affected / exposed	1 / 13 (7.69%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
TOOTHACHE			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
DRY SKIN			
subjects affected / exposed	2 / 13 (15.38%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	2	2	0
ECZEMA			

subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PAIN OF SKIN			
subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
PRURITUS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 13 (0.00%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
RASH MACULAR			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
RASH			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PURPURA SENILE			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
SKIN ULCER			
subjects affected / exposed	0 / 13 (0.00%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Renal and urinary disorders			
HAEMATURIA			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
MICTURITION URGENCY			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
URINARY RETENTION			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Endocrine disorders			
ADRENAL INSUFFICIENCY			

subjects affected / exposed	0 / 13 (0.00%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
CUSHING'S SYNDROME			
subjects affected / exposed	1 / 13 (7.69%)	2 / 19 (10.53%)	1 / 6 (16.67%)
occurrences (all)	1	2	1
Musculoskeletal and connective tissue disorders			
BONE PAIN			
subjects affected / exposed	1 / 13 (7.69%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
BACK PAIN			
subjects affected / exposed	0 / 13 (0.00%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
ARTHRALGIA			
subjects affected / exposed	1 / 13 (7.69%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	1	3	0
GROIN PAIN			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 13 (0.00%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	0	4	0
OSTEONECROSIS OF JAW			
subjects affected / exposed	1 / 13 (7.69%)	2 / 19 (10.53%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
MYALGIA			
subjects affected / exposed	2 / 13 (15.38%)	3 / 19 (15.79%)	1 / 6 (16.67%)
occurrences (all)	2	3	1
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
FOLLICULITIS			

subjects affected / exposed	0 / 13 (0.00%)	0 / 19 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
NAIL INFECTION			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
MUCOSAL INFECTION			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
PROSTATE INFECTION			
subjects affected / exposed	2 / 13 (15.38%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
PNEUMONIA			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
SPINAL CORD INFECTION			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
SUPERINFECTION			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 13 (7.69%)	4 / 19 (21.05%)	0 / 6 (0.00%)
occurrences (all)	5	5	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	1 / 13 (7.69%)	3 / 19 (15.79%)	1 / 6 (16.67%)
occurrences (all)	1	3	1
DEHYDRATION			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

HYPERGLYCAEMIA			
subjects affected / exposed	1 / 13 (7.69%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
HYPERKALAEMIA			
subjects affected / exposed	3 / 13 (23.08%)	7 / 19 (36.84%)	0 / 6 (0.00%)
occurrences (all)	3	13	0
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
HYPOALBUMINAEMIA			
subjects affected / exposed	1 / 13 (7.69%)	0 / 19 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 13 (0.00%)	4 / 19 (21.05%)	0 / 6 (0.00%)
occurrences (all)	0	4	0
HYPONATRAEMIA			
subjects affected / exposed	1 / 13 (7.69%)	7 / 19 (36.84%)	0 / 6 (0.00%)
occurrences (all)	2	11	0
HYPOKALAEMIA			
subjects affected / exposed	3 / 13 (23.08%)	1 / 19 (5.26%)	2 / 6 (33.33%)
occurrences (all)	3	1	3
STEROID DIABETES			
subjects affected / exposed	0 / 13 (0.00%)	1 / 19 (5.26%)	0 / 6 (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
11 January 2022	Amendment 15. Global: • Protocol was harmonised for Finland, Italy, Spain, France and Denmark. There were no study treatment given to any patient in Italy and Spain.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
18 March 2020	The recruitment was temporarily paused in all sites on 18th March 2020 due to the COVID-19 pandemic. At the time there were only 4 patients with PC on study treatment and 1 participant in the post-treatment period of the trial. The recruitment was re-started 7th May 2020.	07 May 2020
01 December 2021	Enrolment to the STESIDES trial was discontinued, even if the patients in the trial were allowed to continue as long as they benefited from the treatment. Another molecule that has the same mode of action was favoured because it was somewhat more advanced in the development and the clinical data of both projects appeared very comparable. No maximum tolerated dose was achieved in the trial, and Part 2 was not initiated.	-

Notes:

Limitations and caveats

None reported