Clinical trial results:
Phase II Trial With Autologous Dendritic Cell Vaccination in Patients With Stage II-III HER2 Negative Breast Cancer

Summary

EudraCT number	2009-017402-36
Trial protocol	ES
Global end of trial date	02 August 2017

Results information

Result version number	v1 (current)
This version publication date	11 January 2022
First version publication date	11 January 2022

Trial information

Trial identification

Sponsor protocol code	DEND/CM

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01431196
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Clinica Universidad de Navarra
Sponsor organisation address	AVENIDA PÍO XII, Nº 36, PAMPLONA/IRUÑA, Spain, 31008
Public contact	UCEC, Clinica Universidad de Navarra, 34 948 255 400, ucicec@unav.es
Scientific contact	UCEC, Clinica Universidad de Navarra, 34 948 255 400, ucicec@unav.es

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	12 August 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 August 2017
Global end of trial reached?	Yes
Global end of trial date	02 August 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Pathologic complete response (pCR) in the breast and the axilla.

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 February 2011
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: 21
Worldwide total number of subjects	21
EEA total number of subjects	21

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)	21
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

22 patiens, 18 years and older

Pre-assignment

Screening details:

22 patients were included of which 21 completed the study.
One patient, once recruited, did not continue in the study by her own decision.

Period 1

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

Arms

Arm title	Treatment

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Autologous dendritic cell
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intradermal use

Dosage and administration details:

The main variable, pathological response of the tumor to chemotherapy, will be calculated after surgery after having received neoadjuvant chemotherapy and at least 4 doses of vaccines.
The dosis is 5-10 x 10E6 units.

Number of subjects in period 1	Treatment
Started	21
Completed	21

Baseline characteristics

Reporting groups	
Reporting group title	Treatment period

Reporting group description: -

Reporting group values	Treatment period	Total	
Number of subjects	21	21	
Age categorical Units: Subjects			
Adults (18-64 years)	21	21	
Gender categorical Units: Subjects			
Female	21	21	

End points

End points reporting groups

Reporting group title	Treatment

Reporting group description: -

Primary: Pathological Complete Response

End point title	Pathological Complete Response[1]

End point description:

End point type	Primary

End point timeframe:

Three years from the last vaccine received during the trial.

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: It is primarily a descriptive statistic.

End point values	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: Number of patients	6			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: During the treatment and follow-up of patients	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.1
Reporting groups	
Reporting group title	Experimental group

Reporting group description: -

Serious adverse events	Experimental group		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 21 (4.76%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Experimental group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 21 (100.00%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	2		
Hot flush			
subjects affected / exposed	5 / 21 (23.81%)		
occurrences (all)	5		
Hypotension			

subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Thrombophlebitis			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Phlebitis			
subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Dependent rubor			
subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Pallor			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	21 / 21 (100.00%)		
occurrences (all)	35		
Swelling			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	8 / 21 (38.10%)		
occurrences (all)	10		
Mucosal inflammation			
subjects affected / exposed	20 / 21 (95.24%)		
occurrences (all)	36		
Oedema			
subjects affected / exposed	15 / 21 (71.43%)		
occurrences (all)	20		
Temperature regulation disorder			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Reproductive system and breast disorders			

Vulvovaginal dryness			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	11 / 21 (52.38%)		
occurrences (all)	14		
Catarrh			
subjects affected / exposed	9 / 21 (42.86%)		
occurrences (all)	9		
Epistaxis			
subjects affected / exposed	3 / 21 (14.29%)		
occurrences (all)	3		
Pharyngitis			
subjects affected / exposed	3 / 21 (14.29%)		
occurrences (all)	4		
Rhinitis			
subjects affected / exposed	4 / 21 (19.05%)		
occurrences (all)	5		
Rhinorrhoea			
subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Psychiatric disorders			
Feeling of despair			
subjects affected / exposed	4 / 21 (19.05%)		
occurrences (all)	4		
Affect lability			
subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Depression			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Nervous system disorders			
Insomnia			
subjects affected / exposed	8 / 21 (38.10%)		
occurrences (all)	8		

Headache			
subjects affected / exposed	11 / 21 (52.38%)		
occurrences (all)	13		
Anxiety			
subjects affected / exposed	3 / 21 (14.29%)		
occurrences (all)	3		
Dizziness			
subjects affected / exposed	5 / 21 (23.81%)		
occurrences (all)	5		
Neuropathy peripheral			
subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Peripheral sensory neuropathy			
subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	3		
Parosmia			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Sciatica			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Neurological decompensation			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Paraesthesia			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	12 / 21 (57.14%)		
occurrences (all)	17		
Lymphopenia			
subjects affected / exposed	11 / 21 (52.38%)		
occurrences (all)	14		
Thrombocytopenia			

subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Neutropenia			
subjects affected / exposed	3 / 21 (14.29%)		
occurrences (all)	4		
Leukopenia			
subjects affected / exposed	6 / 21 (28.57%)		
occurrences (all)	8		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Ear infection			
subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Eye disorders			
Lacrimation increased			
subjects affected / exposed	5 / 21 (23.81%)		
occurrences (all)	6		
Visual acuity reduced			
subjects affected / exposed	3 / 21 (14.29%)		
occurrences (all)	3		
Visual impairment			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Abnormal sensation in eye			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Vision blurred			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Blepharitis			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Conjunctival haemorrhage			

subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Blindness			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Gastrointestinal disorders			
Dysgeusia			
subjects affected / exposed	8 / 21 (38.10%)		
occurrences (all)	11		
Nausea			
subjects affected / exposed	20 / 21 (95.24%)		
occurrences (all)	23		
Constipation			
subjects affected / exposed	13 / 21 (61.90%)		
occurrences (all)	18		
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	7 / 21 (33.33%)		
occurrences (all)	10		
Stomatitis			
subjects affected / exposed	8 / 21 (38.10%)		
occurrences (all)	13		
Gastritis			
subjects affected / exposed	12 / 21 (57.14%)		
occurrences (all)	19		
Flatulence			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Abdominal pain upper			
subjects affected / exposed	3 / 21 (14.29%)		
occurrences (all)	4		
Dyspepsia			
subjects affected / exposed	6 / 21 (28.57%)		
occurrences (all)	6		

Diarrhoea			
subjects affected / exposed	10 / 21 (47.62%)		
occurrences (all)	13		
Dry mouth			
subjects affected / exposed	3 / 21 (14.29%)		
occurrences (all)	4		
Abdominal distension			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Odynophagia			
subjects affected / exposed	4 / 21 (19.05%)		
occurrences (all)	4		
Haemorrhoids			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Hepatobiliary disorders			
Hepatotoxicity			
subjects affected / exposed	4 / 21 (19.05%)		
occurrences (all)	6		
Hypertransaminasaemia			
subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	10 / 21 (47.62%)		
occurrences (all)	12		
Rash erythematous			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Rash scarlatiniform			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	10 / 21 (47.62%)		
occurrences (all)	14		
Herpes zoster			

subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Nail dystrophy			
subjects affected / exposed	17 / 21 (80.95%)		
occurrences (all)	22		
Erythema			
subjects affected / exposed	4 / 21 (19.05%)		
occurrences (all)	4		
Skin hyperpigmentation			
subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Nail pigmentation			
subjects affected / exposed	3 / 21 (14.29%)		
occurrences (all)	3		
Dry skin			
subjects affected / exposed	5 / 21 (23.81%)		
occurrences (all)	5		
Skin reaction			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Skin toxicity			
subjects affected / exposed	4 / 21 (19.05%)		
occurrences (all)	5		
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	18 / 21 (85.71%)		
occurrences (all)	27		
Pain in extremity			

subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Pain in jaw			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	5 / 21 (23.81%)		
occurrences (all)	6		
Osteoarthritis			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Conjunctivitis			
subjects affected / exposed	15 / 21 (71.43%)		
occurrences (all)	23		
Oropharyngeal candidiasis			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Oral candidiasis			
subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Gingivitis			
subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	8 / 21 (38.10%)		
occurrences (all)	8		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 January 2011	New participating center.
05 April 2011	Various protocol and HIP modifications
05 March 2012	Modification of the number of patients
04 April 2012	Radiation therapy in centers of origin
05 July 2012	Change of Sponsor
02 November 2012	CAIBER output
02 July 2013	PEI update.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported