



Clinical trial results:

Estudio fase II con inmunoterapia mediante células dendríticas e Hiltonol en pacientes con tumores sólidos.

Summary

EudraCT number	2010-023139-40
Trial protocol	ES
Global end of trial date	19 May 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	CD-2010-01
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01734564
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	31 May 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 May 2017
Global end of trial reached?	Yes
Global end of trial date	19 May 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Tumor response rate assessed by RECIST criteria

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 March 2013
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: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

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)	10
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

It is intended to include patients with advanced solid tumors without conventional treatment. The study has two cohorts. In one of them, treatment with only dendritic cells and Hiltonol will be administered and in the second treatment with radiotherapy will be added.

Pre-assignment

Screening details:

17 subjects are included of which 15 complete the study and 2 are screening failures.
In the first cohort, 10 patients were included, of which 1 was a screening failure.
In the second cohort, 7 patients were included, of which 1 was a screening failure.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1

Arm description:

Hiltonol and autologous dendritic cells

Arm type	Experimental
Investigational medicinal product name	Autologous dendritic cells
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intradermal use

Dosage and administration details:

The expected dose of dendritic cells is 5-10x10E6, resuspended in 0.5-1 ml of physiological saline. If there are not enough cells to complete the treatment, those that are available will be administered, reducing the dose or the number of injections.

Investigational medicinal product name	Hiltonol
Investigational medicinal product code	
Other name	poly-ICLC
Pharmaceutical forms	Injection
Routes of administration	Intratumoral use

Dosage and administration details:

Patients will receive 2 doses of Hiltonol 0.25 mg by intratumoral injection.

Arm title	Cohort 2
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Arm description:

Hiltonol, dendritic cells and radiation

Arm type	Experimental
Investigational medicinal product name	Autologous dendritic cells
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intradermal use

Dosage and administration details:

The expected dose of dendritic cells is 5-10x10E6, resuspended in 0.5-1 ml of physiological saline. If

there are not enough cells to complete the treatment, those that are available will be administered, reducing the dose or the number of injections.

Investigational medicinal product name	Hiltonol
Investigational medicinal product code	
Other name	poly-ICLC
Pharmaceutical forms	Injection
Routes of administration	Intratumoral use

Dosage and administration details:

Patients will receive 2 doses of Hiltonol 0.25 mg by intratumoral injection.

Number of subjects in period 1	Cohort 1	Cohort 2
Started	9	6
Completed	9	6

Baseline characteristics

Reporting groups

Reporting group title	Treatment period
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Reporting group description: -

Reporting group values	Treatment period	Total	
Number of subjects	15	15	
Age categorical			
Units: Subjects			
Adults (18-64 years)	10	10	
From 65-84 years	5	5	
Gender categorical			
Units: Subjects			
Female	7	7	
Male	8	8	

End points

End points reporting groups

Reporting group title	Cohort 1
Reporting group description: Hiltonol and autologous dendritic cells	
Reporting group title	Cohort 2
Reporting group description: Hiltonol, dendritic cells and radiation	

Primary: Response rate

End point title	Response rate ^[1]
End point description:	
End point type	Primary
End point timeframe: 8-10 weeks	

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	Cohort 1	Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	6		
Units: Number of patients				
SD	4	5		
PD	5	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

During treatment.

Adverse event reporting additional description:

The incidence of all treatment-related adverse events is presented.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.1
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Reporting groups

Reporting group title	Cohort 1
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Reporting group description: -

Reporting group title	Cohort 2
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Reporting group description: -

Serious adverse events	Cohort 1	Cohort 2	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 9 (22.22%)	2 / 6 (33.33%)	
number of deaths (all causes)	8	5	
number of deaths resulting from adverse events	0	0	
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	2 / 9 (22.22%)	2 / 6 (33.33%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Cohort 1	Cohort 2	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)	5 / 6 (83.33%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	1 / 9 (11.11%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Vascular disorders			

Hypotension subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 6 (0.00%) 0	
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all) Local reaction subjects affected / exposed occurrences (all) Decreased appetite subjects affected / exposed occurrences (all) Infusion related reaction subjects affected / exposed occurrences (all) Chills subjects affected / exposed occurrences (all)	3 / 9 (33.33%) 3 7 / 9 (77.78%) 7 1 / 9 (11.11%) 1 1 / 9 (11.11%) 1 0 / 9 (0.00%) 0	3 / 6 (50.00%) 3 2 / 6 (33.33%) 2 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 1 / 6 (16.67%) 1	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 6 (0.00%) 0	
Gastrointestinal disorders Vomiting subjects affected / exposed occurrences (all)	2 / 9 (22.22%) 2	1 / 6 (16.67%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 July 2013	New version of IMPD file 09-033.
05 February 2015	New cohort associating radiotherapy with treatment with dendritic cells and hiltonol.
04 February 2016	The possibility of performing tumor biopsies, for research purposes, during the trial treatment is added. The radiotherapy administration scheme is optimized. Errata are corrected in the protocol.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported