Clinical trial results:
Dendritic cell-based immunotherapy for advanced solid tumours of children and young adults

Summary

EudraCT number	2013-003632-71
Trial protocol	ES
Global end of trial date	03 January 2019

Results information

Result version number	v1 (current)
This version publication date	03 November 2021
First version publication date	03 November 2021
Summary attachment (see zip file)	Final report summary (INFORME FINAL-DEND-TIA de 04-05-2021.pdf)

Trial information

Trial identification

Sponsor protocol code	DEND/TIA

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Clínica Universidad de Navarra
Sponsor organisation address	Avda. Pío XII, 36, Pamplona, Spain, 31008
Public contact	UCEC, Clínica Universidad de Navarra, 34 948255 4001142, ucicec@unav.es
Scientific contact	UCEC, Clínica Universidad de Navarra, 34 948255 4001142, 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	01 April 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 January 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study is to evaluate the safety of the proposed treatment in terms of:
- Effects attributable to the generation and administration of dendritic cells
- Adverse effects during treatment
- Autoimmunity

Protection of trial subjects:

- Clinical trial supervised by the CEIm of Navarra
- In accordance with the GCP guidelines
- Patient confidentiality will be safeguarded in accordance with current legislation

Background therapy:

NA

Evidence for comparator:

NA

Actual start date of recruitment	01 July 2014
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy, Ethical reason
Long term follow-up duration	3 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 6
Worldwide total number of subjects	6
EEA total number of subjects	6

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)	1

Adolescents (12-17 years)	2
Adults (18-64 years)	3
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The patients were selected in the Pediatric and Neurosurgery consultations of the Clínica Universidad de Navarra. Patients were recruited between 09-30-14 (first patient) and 10-30-17 (last patient). Screening failures were two patients with CNS tumors that turned out to be low grade, the exclusion criterion set by the trial.

Pre-assignment

Screening details:

NA

Period 1

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

Arms

Arm title	Treatment

Arm description:

The time of administration of the vaccines is different for each type of tumor.
After surgery, treatment for advanced sarcomas includes cycles of chemotherapy every three weeks (x6) that are given concomitantly with vaccines. The administration of vaccines includes 4 vaccines every three weeks 4 vaccines every two months and 4 vaccines every three months. The rest of the vaccines are given without chemotherapy.
For CNS tumors, after surgery, treatment consists of radiation therapy plus chemotherapy. Chemotherapy cycles will be given every 3 weeks (x5). The administration of the vaccines includes 4 vaccines every three weeks, 4 vaccines every two months, and 4 vaccines every three months. The rest of the vaccines are given without chemotherapy.

Arm type	Experimental
Investigational medicinal product name	Dendritic cell-based
Investigational medicinal product code	09-033
Other name	AUTOLOGOUS DENDRITIC CELLS DERIVED FROM MONOCYTES CHARGED WITH AUTOLOGOUS TUMOR LISTING
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

The cells are administered in suspension, at doses between 5x106 and 10x106, of administration repeated intradermal or intranodal.

Number of subjects in period 1	Treatment
Started	6
Completed	6

Baseline characteristics

End points

End points reporting groups

Reporting group title	Treatment

Reporting group description:

The time of administration of the vaccines is different for each type of tumor.
After surgery, treatment for advanced sarcomas includes cycles of chemotherapy every three weeks (x6) that are given concomitantly with vaccines. The administration of vaccines includes 4 vaccines every three weeks 4 vaccines every two months and 4 vaccines every three months. The rest of the vaccines are given without chemotherapy.
For CNS tumors, after surgery, treatment consists of radiation therapy plus chemotherapy. Chemotherapy cycles will be given every 3 weeks (x5). The administration of the vaccines includes 4 vaccines every three weeks, 4 vaccines every two months, and 4 vaccines every three months. The rest of the vaccines are given without chemotherapy.

Primary: Safety

End point title	Safety[1]

End point description:

percentage of AE and relationship with treatment

End point type	Primary

End point timeframe:

4 years.

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: As indicated in the protocol: The main variable of the study is the evaluation of safety. A descriptive analysis of the adverse events observed during the study will be carried out, both in global frequency and per patient, as well as changes in cell populations.

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

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 4 years	
Assessment type	Systematic

Dictionary used	
Dictionary name	none
Dictionary version	0

Reporting groups	
Reporting group title	Treatment

Reporting group description:

The time of administration of the vaccines is different for each type of tumor.
After surgery, treatment for advanced sarcomas includes cycles of chemotherapy every three weeks (x6) that are given concomitantly with vaccines. The administration of vaccines includes 4 vaccines every three weeks 4 vaccines every two months and 4 vaccines every three months. The rest of the vaccines are given without chemotherapy.
For CNS tumors, after surgery, treatment consists of radiation therapy plus chemotherapy. Chemotherapy cycles will be given every 3 weeks (x5). The administration of the vaccines includes 4 vaccines every three weeks, 4 vaccines every two months, and 4 vaccines every three months. The rest of the vaccines are given without chemotherapy.

Serious adverse events	Treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)		
number of deaths (all causes)	5		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)		
General disorders and administration site conditions			
general discomfort			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Fever			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
induration and redness			

subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	5		
headache			
subjects affected / exposed	3 / 6 (50.00%)		
occurrences (all)	3		
odynophagia			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
cough			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
low-grade fever			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
paresthesia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
immobility on right foot			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Itchy throat			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Cold			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
pulpitis			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Social circumstances			
short-term memory failure			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
anxiety			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		

Gastrointestinal disorders abdominal pain subjects affected / exposed occurrences (all) Vomits subjects affected / exposed occurrences (all)	 1 / 6 (16.67%) 2 2 / 6 (33.33%) 2		
Respiratory, thoracic and mediastinal disorders upper respiratory infection subjects affected / exposed occurrences (all)	 1 / 6 (16.67%) 1		
Skin and subcutaneous tissue disorders paronychia subjects affected / exposed occurrences (all) wart infection subjects affected / exposed occurrences (all) chafing subjects affected / exposed occurrences (all) ingrown toenail subjects affected / exposed occurrences (all) pruritus subjects affected / exposed occurrences (all) toe infection subjects affected / exposed occurrences (all)	 2 / 6 (33.33%) 2 1 / 6 (16.67%) 1 1 / 6 (16.67%) 1 1 / 6 (16.67%) 1 1 / 6 (16.67%) 1 1 / 6 (16.67%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

NA

Notes: