Clinical trial results:
T cell therapy for patients with advanced Renal Cell Carcinoma

Summary

EudraCT number	2016-001454-18
Trial protocol	DK
Global end of trial date	31 October 2021

Results information

Result version number	v1 (current)
This version publication date	04 October 2022
First version publication date	04 October 2022

Trial information

Trial identification

Sponsor protocol code	UG1617

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02926053
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Inge Marie Svane
Sponsor organisation address	Borgmester Ib Juuls Vej 25c, Herlev, Denmark, 2730
Public contact	Mette Wassard Yde, National Center for Cancer Immune Therapy, 0045 38689339, mette.wassard.yde@regionh.dk
Scientific contact	Mette Wassard Yde, National Center for Cancer Immune Therapy, 0045 38689339, mette.wassard.yde@regionh.dk

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 October 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 October 2021
Global end of trial reached?	Yes
Global end of trial date	31 October 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate toxicity (according to CTCAE version 4.0) and feasibility.

Protection of trial subjects:

Standard-of-care

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2016
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	Denmark: 5
Worldwide total number of subjects	5
EEA total number of subjects	5

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

Subject disposition

Recruitment

Recruitment details:

Danish patients with renal cell cancer was included in the period March 2017 - September 2019.

Pre-assignment

Screening details:

In total eight patients were found eligible. Five patient were included for treatment. Patients was not included due to clinical progression (1) or patient's wish/received other treatment (2).

Period 1

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

Arms

Arm title	All patients

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Tumor-infiltrating lymphocytes
Investigational medicinal product code	
Other name	TIL
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

TILs were infused day 0. Maximum number of cultured TILs were infused ranging from 46-96 x 10e9 cells

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	Cy
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Cyclophosphamide 60 mg/kg was administered once daily on day -7 and -6

Investigational medicinal product name	Fludarabine phosphate
Investigational medicinal product code	
Other name	Fludara
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Fludarabine phosphate was administered once daily 25 mg/m2 (max 50 mg) at days -5 to -1

Investigational medicinal product name	Interleukin-2
Investigational medicinal product code	
Other name	IL-2, aldesleukin
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

Interleukin-2 was adminstered as an intravenous bolus over 15 minutes at dose 600.000 IE/kg every 8 hours starting from day 0 for a maximum of 15 doses.

Number of subjects in period 1	All patients
Started	5
Completed	5

Baseline characteristics

Reporting groups

Reporting group title	Full trial

Reporting group description: -

Reporting group values	Full trial	Total	
Number of subjects	5	5	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	5	5	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	1	1	
Male	4	4	

Subject analysis sets

Subject analysis set title	Treated patients
Subject analysis set type	Full analysis

Subject analysis set description:
All treated patients

Reporting group values	Treated patients		
Number of subjects	5		
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)	5		
From 65-84 years	0		
85 years and over	0		

Gender categorical Units: Subjects			
Female	1		
Male	4		

End points

End points reporting groups

Reporting group title	All patients
Reporting group description: -	
Subject analysis set title	Treated patients
Subject analysis set type	Full analysis
Subject analysis set description:	
All treated patients	

Primary: Number of patients in which the treatment was tolerable

End point title	Number of patients in which the treatment was tolerable[1]
End point description:	
Number of patients who received treatment according to protocol	
End point type	Primary
End point timeframe:	
Full 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: In this phase I study, the primary end point is tolerability and there is no appropriate statistical test

End point values	All patients			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: patients	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Infusion products with detectable in-vitro anti-tumor responses

End point title	Infusion products with detectable in-vitro anti-tumor responses
End point description:	
End point type	Secondary
End point timeframe:	
Any time after the infusion product has been produced	

End point values	All patients			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: Infusion products	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Objective response rate

End point title	Objective response rate

End point description:

Patients who achieved partial or complete response according to RECIST 1.1 criteria

End point type	Secondary

End point timeframe:

Full trial

End point values	All patients			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: Patients	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Full trial	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	25

Reporting groups	
Reporting group title	Treated patients

Reporting group description: -

Serious adverse events	Treated patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 5 (20.00%)		
number of deaths (all causes)	5		
number of deaths resulting from adverse events	0		
Blood and lymphatic system disorders			
Hypotension			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Treated patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)		
Nervous system disorders			
Confusional state			
subjects affected / exposed	2 / 5 (40.00%)		
occurrences (all)	2		
Hallucination			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	5 / 5 (100.00%)		
occurrences (all)	5		
Pain			
subjects affected / exposed	4 / 5 (80.00%)		
occurrences (all)	4		
Performance status decreased			
subjects affected / exposed	5 / 5 (100.00%)		
occurrences (all)	5		
Weight increased			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	5 / 5 (100.00%)		
occurrences (all)	5		
Petechiae			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Anaemia			
subjects affected / exposed	5 / 5 (100.00%)		
occurrences (all)	5		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	3 / 5 (60.00%)		
occurrences (all)	3		
Diarrhoea			
subjects affected / exposed	4 / 5 (80.00%)		
occurrences (all)	4		
Nausea			
subjects affected / exposed	5 / 5 (100.00%)		
occurrences (all)	5		
Stomatitis			
subjects affected / exposed	3 / 5 (60.00%)		
occurrences (all)	3		
Vomiting			

subjects affected / exposed occurrences (all) Melaena subjects affected / exposed occurrences (all)	2 / 5 (40.00%) 2 1 / 5 (20.00%) 1		
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	 5 / 5 (100.00%) 5		
Skin and subcutaneous tissue disorders Rash maculo-papular subjects affected / exposed occurrences (all) Dry skin subjects affected / exposed occurrences (all)	 2 / 5 (40.00%) 2 5 / 5 (100.00%) 5		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Myalgia subjects affected / exposed occurrences (all)	 1 / 5 (20.00%) 1 3 / 5 (60.00%) 3		
Infections and infestations Infection subjects affected / exposed occurrences (all)	 4 / 5 (80.00%) 4		

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

None reported