Clinical trial results:
Intratumoral Influenza Vaccine for Early Colorectal Cancer

Summary

EudraCT number	2020-000725-27
Trial protocol	DK
Global end of trial date	01 September 2021

Results information

Result version number	v1 (current)
This version publication date	28 June 2023
First version publication date	28 June 2023

Trial information

Trial identification

Sponsor protocol code	2020-000725-27

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Zealand University Hospital
Sponsor organisation address	LYkkebækvej 1, Køge, Denmark,
Public contact	Research fellow, Center for Surgical Science, Department of Surgery, Zealand University Hospital, 0045 31429929, mgog@regionsjaelland.dk
Scientific contact	Research fellow, Center for Surgical Science, Department of Surgery, Zealand University Hospital, 0045 31429929, mgog@regionsjaelland.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	01 February 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 September 2021
Global end of trial reached?	Yes
Global end of trial date	01 September 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Primary:
To investigate if intratumoral influenza vaccine is a safe treatment modality for tumor down staging prior to intended curative surgery in patients undergoing treatment for colorectal cancer.

Protection of trial subjects:

Treated in routine care

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 February 2021
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: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	2
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited after the colorectal cancer MDT conference

Pre-assignment

Screening details:

Patients were screened at the colorectal cancer MDT conference

Period 1

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

Blinding implementation details:

This was a non-blinded single arm study

Arms

Arm title	Active

Arm description:

Treatment with intratumoral influenza vaccine

Arm type	Experimental
Investigational medicinal product name	InfluVacTetra
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intratumoral use

Dosage and administration details:

A single dose influenza vaccine (50 microliter) that was mixed with 150 microliter saline

Number of subjects in period 1	Active
Started	10
Completed	10

Baseline characteristics

Reporting groups

Reporting group title	Full study

Reporting group description: -

Reporting group values	Full study	Total	
Number of subjects	10	10	
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)	2	2	
From 65-84 years	8	8	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	3	3	
Male	7	7	

Subject analysis sets

Subject analysis set title	Full analysis
Subject analysis set type	Full analysis

Subject analysis set description:

Baseline characteristics
Tumor-infiltrating lymphocytes
mRNA gene expression
Spatial protein expression
FLOW analysis of blood

Reporting group values	Full analysis		
Number of subjects	10		
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)	2		
From 65-84 years	8		

85 years and over	0		

Gender categorical Units: Subjects			
Female	3		
Male	7		

End points

End points reporting groups

Reporting group title	Active
Reporting group description:	
Treatment with intratumoral influenza vaccine	
Subject analysis set title	Full analysis
Subject analysis set type	Full analysis
Subject analysis set description:	
Baseline characteristics Tumor-infiltrating lymphocytes mRNA gene expression Spatial protein expression FLOW analysis of blood	

Primary: Safety of treatment (CTCAE v4)

End point title	Safety of treatment (CTCAE v4)
End point description:	
End point type	Primary
End point timeframe:	
Day 0-14	

End point values	Active	Full analysis		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	10	10		
Units: Events				
Adverse events	1	1		
Serious adverse events	0	0		

Statistical analyses

Statistical analysis title	Confidence interval for adverse events
Comparison groups	Active v Full analysis
Number of subjects included in analysis	20
Analysis specification	Post-hoc
Analysis type	other[1]
Parameter estimate	Confidence interval
Point estimate	10
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	30

Notes:

[1] - The investigators performed af statistical analysis of the confidence interval for adverse events as specified in "Simon, S. Confidence interval with zero events. http://new.pmean.com/zero-events/ (2001)"

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Day 0-14	
Adverse event reporting additional description: CTCAE v4	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4

Reporting groups	
Reporting group title	Experimental arm

Reporting group description: -

Serious adverse events	Experimental arm		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Experimental arm		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 10 (10.00%)		
General disorders and administration site conditions			
Fever	Additional description: A mild fever that subsided without intervention		
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	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

None reported