Clinical trial results:
Feasibility and efficacy of adjuvant gemcitabine chemotherapy after liver transplantation for proximal bile duct cancer

Summary

EudraCT number	2010-020480-21
Trial protocol	DE
Global end of trial date	21 April 2021

Results information

Result version number	v1 (current)
This version publication date	16 July 2022
First version publication date	16 July 2022

Trial information

Trial identification

Sponsor protocol code	pro-duct001

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Charité – Universitätsmedizin Berlin
Sponsor organisation address	Charité Platz 1, Berlin, Germany, 10117
Public contact	Prof. Dr. Johann Pratschke, Chirurgische Klinik, Campus Virchow-Klinikum, Augustenburger Platz , 13353 Berlin., 030 450 552001, moritz.schmelzle@charite.de
Scientific contact	Prof. Dr. Moritz Schmelzle, Chirurgische Klinik Poliklinik, 030 450 652336, moritz.schmelzle@charite.de

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	Interim
Date of interim/final analysis	21 April 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 April 2021
Global end of trial reached?	Yes
Global end of trial date	21 April 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To investigate, if adjuvant gemcitabine chemotherapy is feasible in ≥ 85 % of patients after liver transplantation.

Protection of trial subjects:

Depending on the postoperative course, the adjuvant chemotherapy is intended to start 4 to 8 weeks after liver transplantation, but not later than at the end of the 10th week after transplantation. If patients are unable to be randomized until 10 weeks after liver transplantation, they will be excluded from the study and not included in the per-protocol analysis. Toxicities are graded according to the World Health Organization (WHO).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 July 2010
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	Germany: 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)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	6
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

From July 2012 to September 2016, 12 patients from four German transplant centers.

Pre-assignment

Screening details:

to be assessed for eligibility. n = 150
to be listed for transplantation: n = 80
to undergo liver transplantation: n = 60
to be randomized (allocated to trial: adjuvant therapy versus obersvation): n = 45

Period 1

Period 1 title	Baseline and trial period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

6 participants were recruited to the study. No final analysis was done as the trial was terminated early due to difficulties in recruitment.

Arms

Are arms mutually exclusive?	Yes
Arm title	Experimental Group

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for infusion
Routes of administration	Infusion

Dosage and administration details:

800 mg/m² in cycles 1 and . if tolerated the dosage cycles 3 to 6 is increased to 1000 mg/m² per application

Arm title	Control group

Arm description:

Patients in the control group receive no adjuvant treatment, which represents the standard medical treamtnet for bile duct cancers.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Experimental Group	Control group
Started	3	3
Completed	3	3

Baseline characteristics

End points

End points reporting groups

Reporting group title	Experimental Group
Reporting group description: -	
Reporting group title	Control group

Reporting group description:

Patients in the control group receive no adjuvant treatment, which represents the standard medical treamtnet for bile duct cancers.

Primary: Final Endpoint

End point title	Final Endpoint[1]

End point description:

End point type	Primary

End point timeframe:

Only 6 participants were recruited to the study, no analysis was carried out. Trial was terminated early due to problems with recruitment.

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: Only 6 participants were recruited to the study, no analysis was carried out. Trial was terminated early due to problens with recruitment

End point values	Experimental Group	Control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3[2]	3[3]		
Units: unit(s)				
number (not applicable)	0	0		

Notes:

[2] - Only 6 participants were recruited to the study, no analysis was carried out. Trial was terminated e

[3] - Only 6 participants were recruited to the study, no analysis was carried out. Trial was terminated e

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 12 months after liver transpantations	
Assessment type	Systematic

Dictionary used	
Dictionary name	own
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: no AEs and SAEs were reported and due to premature ending.

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.

-Recruitment difficulties
-terminated prematurely
-no final conclusion
-constellation necessary for liver transplantation is very rarely in PHC
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Notes: