Clinical trial results:
Catheter based adjuvant intraperitoneal chemotherapy for carcinomatosis.

Summary

EudraCT number	2014-000882-34
Trial protocol	BE
Global end of trial date	12 November 2015

Results information

Result version number	v1 (current)
This version publication date	28 July 2021
First version publication date	28 July 2021
Summary attachment (see zip file)	Summary (2014-000882-34.docx)

Trial information

Trial identification

Sponsor protocol code	AGO/2014/002

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Ghent University Hospital
Sponsor organisation address	Corneel Heymanslaan 10, Ghent, Belgium, 9000
Public contact	Hiruz CTU, University Hospital Ghent, +32 93320500, hiruz.ctu@uzgent.be
Scientific contact	Hiruz CTU, University Hospital Ghent, +32 93320500, hiruz.ctu@uzgent.be

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	12 November 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 November 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the feasibility and safety of adjuvant, catheter based intraperitoneal chemotherapy in patients with minimal residual disease after cytoreductive surgery for carcinomatosis from GI origin.

Protection of trial subjects:

Ethics review and approval, informed consent, supportive care and routine monitoring.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 June 2014
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	Belgium: 2
Worldwide total number of subjects	2
EEA total number of subjects	2

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)	1
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

2 patients were screened from 05-06-2014 till 12-11-2015. 2 patients were enrolled and randomised. 0 patients were included and completed the trial. End of trial notification was dated 12-11-2015 (last patient last visit) and submitted to EC and CA 12/12/2017.

Pre-assignment

Screening details:

INCLUSION CRITERIA:
Peritoneal carcinomatosis from GI origin (appendix, colon, small bowel, stomach)
- Resectable disease
- No or minimal systemic or extra-abdominal disease or metastatic spread
- Written informed consent

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	Baseline

Arm description:

Baseline data for the study, as the study only has 1 arm.

Arm type	Baseline arm

No investigational medicinal product assigned in this arm

Arm title	Treatment

Arm description: -

Arm type	Experimental
Investigational medicinal product name	5-fluorouracil
Investigational medicinal product code	
Other name	Fluracedyl
Pharmaceutical forms	Infusion
Routes of administration	Intraperitoneal use

Dosage and administration details:

5-fluorouracil 600 mg/m2 biweekly, total of 9 cycles

Number of subjects in period 1	Baseline	Treatment
Started	2	2
Completed	2	0
Not completed	0	2
Adverse event, serious fatal	-	1
Lost to follow-up	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	2	2	
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)	1	1	
From 65-84 years	1	1	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	0	0	
Male	2	2	

End points

End points reporting groups

Reporting group title	Baseline

Reporting group description:

Baseline data for the study, as the study only has 1 arm.

Reporting group title	Treatment

Reporting group description: -

Primary: termination of IP chemotherapy due to complications or adverse events.

End point title	termination of IP chemotherapy due to complications or adverse events.[1]

End point description:

End point type	Primary

End point timeframe:

Until end oif treatment due to complications or adverse events

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: No statistical analysis available.

End point values	Baseline	Treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[2]	0[3]		
Units: N/A				

Notes:

[2] - Baseline arm.

[3] - Drop-out of patients.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Overall study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24

Reporting groups

Reporting group title	Baseline

Reporting group description:

Baseline data for the study, as the study only has 1 arm.

Reporting group title	Treatment

Reporting group description:

Treatment arm that received 5-fluorouracil (Fluracedyl) 600 mg/m2 intraperitoneal.

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 non-serious adverse events were recorded for the participating patients.

Serious adverse events	Baseline	Treatment	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events	0		
General disorders and administration site conditions			
exploratieve laparotomy: surgical stenting			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Death	Additional description: Disease progression - rapidly failing health - death		
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	

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

Non-serious adverse events	Baseline	Treatment	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	

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.

2 patients prematurely discontinued. Only 2 patients were included because the potential number of suitable candidates that could be a candidate for this therapy was overestimated.

Notes: