



## 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
<b>Arm title</b>	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	
<b>Arm title</b>	Treatment

Arm description: -

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

Dosage and administration details:

5-fluorouracil 600 mg/m<sup>2</sup> 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. <sup>[1]</sup>
-----------------	---

End point description:

End point type	Primary
----------------	---------

End point timeframe:

Until end of 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 <sup>[2]</sup>	0 <sup>[3]</sup>		
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<sup>[1]</sup>

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/m<sup>2</sup> 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			
explorative 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 %

<b>Non-serious adverse events</b>	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: