Clinical trial results:
Effect of intravenous replenishment of iron in the preoperative management of anemia in patients with colon cancer: RIPAC-trial

Summary

EudraCT number	2018-004213-41
Trial protocol	BE
Global end of trial date	21 June 2021

Results information

Result version number	v1 (current)
This version publication date	08 August 2024
First version publication date	08 August 2024
Summary attachment (see zip file)	Final Study Report (2018-004213-41_Final_Study_Report.pdf)

Trial information

Trial identification

Sponsor protocol code	RIPAC

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	C. Heymanslaan 10, Gent, Belgium, 9000
Public contact	Clinical Trial Unit, Health, Innovation and Research Institute, 32 93320500, hiruz.ctu@uzgent.be
Scientific contact	Clinical Trial Unit, Health, Innovation and Research Institute, 093321539 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	09 May 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 June 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1. To investigate the increase in preoperative Hb after intravenous iron substitution compared with no iron substitution in patients with colon cancer and iron deficiency anemia who are eligible for surgery.

Protection of trial subjects:

See attachment Final Study Report

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 2019
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: 7
Worldwide total number of subjects	7
EEA total number of subjects	7

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)	0
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

See attachment Final Study Report

Pre-assignment

Screening details:

See attachment Final Study Report

Period 1

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

Blinding implementation details:

See attachment Final Study Report

Arms

Are arms mutually exclusive?	Yes
Arm title	Group with iron subsitution

Arm description:

See attachment Final Study Report

Arm type	Active comparator
Investigational medicinal product name	Injectafer
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

See attachment Final Study Report

Arm title	Group without iron subsitution

Arm description:

See attachment Final Study Report

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Group with iron subsitution	Group without iron subsitution
Started	2	5
Completed	1	4
Not completed	1	1
Adverse event, serious fatal	-	1
See attachment Final Study Report	1	-

Baseline characteristics

End points

End points reporting groups

Reporting group title	Group with iron subsitution
Reporting group description: See attachment Final Study Report	
Reporting group title	Group without iron subsitution
Reporting group description: See attachment Final Study Report	

Primary: Primary

End point title	Primary[1]
End point description: See attachment Final Study Report	
End point type	Primary
End point timeframe: See attachment Final Study Report	

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: See attachment Final Study Report

End point values	Group with iron subsitution	Group without iron subsitution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	5		
Units: Mean Hb increase				
number (not applicable)	2	5		

Statistical analyses

No statistical analyses for this end point

Secondary: Secondary

End point title	Secondary
End point description: See attachment Final Study Report	
End point type	Secondary
End point timeframe: During the study	

End point values	Group with iron subsitution	Group without iron subsitution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	5		
Units: Subjects				
number (not applicable)	2	5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: During the study	
Adverse event reporting additional description: See attachment Final Study Report	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 1 %

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: See attachment Final Study Report

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