Clinical trial results:
An open-label, multicentre, randomised, 2-arm study to investigate the comparative efficacy and safety of intravenous ferric carboxymaltose versus oral iron for the treatment of iron deficiency anaemia in pregnant women

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2009-017658-11
Trial protocol	DE SE
Global end of trial date	16 May 2014

Results information

Result version number	v2 (current)
This version publication date	29 July 2016
First version publication date	06 August 2015
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	FER-ASAP-2009-01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01131624
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Vifor Pharma
Sponsor organisation address	Flughofstrasse 61, Glattbrugg, Switzerland, CH-8152
Public contact	Medical Information, Vifor Pharma, +41 58 851 8222, medinfo@viforpharma.com
Scientific contact	Medical Information, Vifor Pharma, +41 58 851 8222, medinfo@viforpharma.com

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	24 April 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 May 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary Objective

• To evaluate the efficacy of ferric carboxymaltose (FCM) compared to oral iron in the treatment of iron deficiency anaemia (IDA) in pregnant women of the second and third trimester.

Protection of trial subjects:

The study was conducted in accordance with the principles of the Declaration of Helsinki, including amendments in force up to and including the time the study was conducted.
The study was conducted in compliance with the International Conference on Harmonisation (ICH) E6 Guideline for Good Clinical Practice (GCP), Committee for Proprietary Medicinal Products Guideline (CPMP/ICH/135/95), and compliant with the EU Clinical Trial Directive (Directive 2001/20/EC and 2005/28/EC).
Before each subject was admitted to the study, a signed and dated informed consent was obtained from the subject (or his/her legally authorised representative) according to the regulatory and legal requirements of the participating country. This consent form was retained by the Investigator as part of the study records. A copy of the document was provided to the subject. No investigations specifically required for the study were conducted until valid consent was obtained. The content of the informed consent was in accordance with the current revision of the Declaration of Helsinki, current ICH and GCP guidelines, and Vifor Pharma - Vifor (International) Inc. policy.
The Investigator explained the aims, methods, reasonably anticipated benefits and potential hazards of the study and any potential discomforts. Subjects were informed that their participation in the study was entirely voluntary and would have no effect on clinical care otherwise available and that they could withdraw consent to participate at any time without penalty or loss of further medical treatment. Subjects were told that Competent Authorities and authorised persons could examine their records but that personal information would be treated as strictly confidential and would not be publicly available. Revisions to the ICF made to reflect the changes to the protocol were reviewed and approved by the appropriate IEC, and signed by all subjects, both subsequently and/or previously enrolled in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 May 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Sweden: 14
Country: Number of subjects enrolled	Switzerland: 9
Country: Number of subjects enrolled	Turkey: 4
Country: Number of subjects enrolled	Russian Federation: 124
Country: Number of subjects enrolled	Korea, Republic of: 90
Country: Number of subjects enrolled	Singapore: 3

Country: Number of subjects enrolled	Australia: 8
Worldwide total number of subjects	252
EEA total number of subjects	14

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)	252
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were screened at 34 sites and randomised at 29 sites in 7 countries.

Pre-assignment

Screening details:

At total of 774 patients were screened and 252 randomized. Five randomized patients did not receive study drug.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Ferric carboxymaltose

Arm description:

Subjects with body weight ≥66 kg received an infusion of 1,000 mg iron as ferric carboxymaltose (FCM) and after 1 week a further 500 mg iron as FCM, depending on haemoglobin (Hb) at screening. For subjects with body weight <66 kg, 2 to 3 infusions of 500 mg iron as FCM were administered within 2 weeks from baseline, depending on Hb at screening. Total doses of FCM were either 1,000 mg or 1,500 mg.

Arm type	Experimental
Investigational medicinal product name	Ferric carboxymaltose
Investigational medicinal product code	
Other name	Ferinject, FCM
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The maximum single dose of FCM that can be administered by intravenous infusion is 20 mL (1,000 mg iron) but should not exceed 15 mg of iron per kg of body weight. This means that for subjects with a body weight below 66 kg a maximal dose of 500 mg iron per infusion is allowed. The total required dose (1,000-1,500 mg) was administrated before Visit 3 (Day 21).

Arm title	Oral iron

Arm description:

100 mg ferrous sulphate capsules taken twice a day for a total daily dose of 200 mg for up to 12 weeks.

Arm type	Active comparator
Investigational medicinal product name	Oral iron
Investigational medicinal product code	
Other name	ferrous sulphate, Plastufer®
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Each capsule contained 100 mg iron and was taken twice per day for a total daily dose of 200 mg iron for up to 12 weeks. Generally oral iron should be taken between meals i.e., 2 hours before or 1 hour after a meal, for maximum absorption but could be taken with or after meals, if necessary, to minimise adverse GI effects.

Number of subjects in period 1	Ferric carboxymaltose	Oral iron
Started	126	126
Completed	111	110
Not completed	15	16
Consent withdrawn by subject	8	6
Adverse event, non-fatal	1	7
Lost to follow-up	4	2
unspecified	1	-
Protocol deviation	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Ferric carboxymaltose
Reporting group description:	
Subjects with body weight ≥66 kg received an infusion of 1,000 mg iron as ferric carboxymaltose (FCM) and after 1 week a further 500 mg iron as FCM, depending on haemoglobin (Hb) at screening. For subjects with body weight <66 kg, 2 to 3 infusions of 500 mg iron as FCM were administered within 2 weeks from baseline, depending on Hb at screening. Total doses of FCM were either 1,000 mg or 1,500 mg.	
Reporting group title	Oral iron
Reporting group description:	
100 mg ferrous sulphate capsules taken twice a day for a total daily dose of 200 mg for up to 12 weeks.	

Reporting group values	Ferric carboxymaltose	Oral iron	Total
Number of subjects	126	126	252
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	126	126	252
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	31.4	30.9	
standard deviation	± 5.77	± 5.39	-
Gender categorical Units: Subjects			
Female	126	126	252
Male	0	0	0

End points

End points reporting groups

Reporting group title	Ferric carboxymaltose
Reporting group description:	
Subjects with body weight ≥66 kg received an infusion of 1,000 mg iron as ferric carboxymaltose (FCM) and after 1 week a further 500 mg iron as FCM, depending on haemoglobin (Hb) at screening. For subjects with body weight <66 kg, 2 to 3 infusions of 500 mg iron as FCM were administered within 2 weeks from baseline, depending on Hb at screening. Total doses of FCM were either 1,000 mg or 1,500 mg.	
Reporting group title	Oral iron
Reporting group description:	
100 mg ferrous sulphate capsules taken twice a day for a total daily dose of 200 mg for up to 12 weeks.	
Subject analysis set title	Ferric carboxymaltose - Full analysis set
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects randomized to the FCM treatment arm who received at least 1 dose of randomised treatment and attended at least 1 post-baseline visit.	
Subject analysis set title	Oral iron - Full analysis set
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects randomized to the oral iron treatment arm who received at least 1 dose of randomised treatment and attended at least 1 post-baseline visit.	
Subject analysis set title	Ferric carboxymaltose - Safety set
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to the FCM treatment arm who received at least 1 dose of randomised treatment.	
Subject analysis set title	Oral Iron - Safety set
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to the oral iron treatment arm who received at least 1 dose of randomized treatment.	

Primary: Change from Baseline to Week 3 in Haemoglobin

End point title	Change from Baseline to Week 3 in Haemoglobin
End point description:	
Baseline was defined as the last non-missing value prior to dosing including Day 1.	
End point type	Primary
End point timeframe:	
Day 0 (baseline), Week 3	

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	114[1]	108[2]		
Units: g/dL				
least squares mean (confidence interval 95%)	1.14 (0.98 to 1.3)	1.01 (0.85 to 1.18)		

Notes:

[1] - Full analysis set but restricted to those subjects that had a Week 3 visit.

[2] - Full analysis set but restricted to those subjects that had a Week 3 visit.

Statistical analyses

Statistical analysis title	HB Change from Baseline

Statistical analysis description:

Difference is calculated as FCM Hb level minus oral iron Hb levels. Thus a positive difference indicates a higher Hb level in the FCM arm.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	222
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.247 [3]
Method	ANCOVA
Parameter estimate	Difference of Least-Squares-Means (LSM)
Point estimate	0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.09
upper limit	0.34
Variability estimate	Standard error of the mean
Dispersion value	0.109

Notes:

[3] - The significance level is set at a 2-sided alpha of 0.05. ANCOVA includes factors for treatment, pooled country and Hb level at baseline.

Secondary: Change from Baseline to Week 3, 6, 9, and 12 in Haemoglobin Using a Repeated Measures Model

End point title	Change from Baseline to Week 3, 6, 9, and 12 in Haemoglobin Using a Repeated Measures Model

End point description:

Baseline was defined as the last non-missing value prior to dosing including Day 1. Least-Squares-Means estimates were taken from the repeated measures model.

End point type	Secondary

End point timeframe:

Day 0 (baseline), Weeks 3, 6, 9, 12

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121[4]	115[5]		
Units: g/L				
least squares mean (confidence interval				

95%)				
Week 3 (n=114, 108)	1.16 (1 to 1.32)	1.04 (0.88 to 1.21)		
Week 6 (n=109, 97)	1.68 (1.5 to 1.87)	1.4 (1.2 to 1.6)		
Week 9 (n=68, 61)	2.07 (1.86 to 2.28)	1.99 (1.77 to 2.21)		
Week 12 (n=34, 32)	2.57 (2.2 to 2.94)	2.15 (1.77 to 2.53)		

Notes:

[4] - # patients analyzed for each timepoint are reported within the category title.

[5] - # patients analyzed for each timepoint are reported within the category title.

Statistical analyses

Statistical analysis title	Hb Change from Baseline: Week 3

Statistical analysis description:

Difference is calculated as FCM Hb level minus oral iron Hb levels. Thus a positive difference indicates a higher Hb level in the FCM arm. Subjects in this analysis is 222.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.274 [6]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.34
Variability estimate	Standard error of the mean
Dispersion value	0.109

Notes:

[6] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Hb Change from Baseline: Week 6

Statistical analysis description:

Difference is calculated as FCM Hb level minus oral iron Hb levels. Thus a positive difference indicates a higher Hb level in the FCM arm. Subjects in this analysis is 206.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.032 [7]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	0.28

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.02
upper limit	0.55
Variability estimate	Standard error of the mean
Dispersion value	0.132

Notes:

[7] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Hb Change from Baseline: Week 9

Statistical analysis description:

Difference is calculated as FCM Hb level minus oral iron Hb levels. Thus a positive difference indicates a higher Hb level in the FCM arm. Subjects in this analysis is 129.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.559 [8]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.21
upper limit	0.38
Variability estimate	Standard error of the mean
Dispersion value	0.15

Notes:

[8] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Hb Change from Baseline: Week 12

Statistical analysis description:

Difference is calculated as FCM Hb level minus oral iron Hb levels. Thus a positive difference indicates a higher Hb level in the FCM arm. Subjects in this analysis is 66.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.118 [9]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	0.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.11
upper limit	0.95

Variability estimate	Standard error of the mean
Dispersion value	0.265

Notes:

[9] - The significance level is set at a 2-sided alpha of 0.05.

Secondary: Change from Baseline to Week 3, 6, 9, 12 and Last Visit Prior to Delivery in Serum Ferritin

End point title	Change from Baseline to Week 3, 6, 9, 12 and Last Visit Prior to Delivery in Serum Ferritin

End point description:

Baseline was defined as the last non-missing value prior to dosing including Day 1. Least-Squares-Means estimates were taken from the repeated measures model for weeks 3, 6, 9 and 12, and from a ANCOVA results model for the last visit prior to delivery.

End point type	Secondary

End point timeframe:

Day 0 (baseline), Weeks 3, 6, 9, 12, last visit prior to delivery (longest is Week 25)

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121[10]	115[11]		
Units: mcg/L				
least squares mean (confidence interval 95%)				
Week 3 (n=116, 110)	301.81 (274.81 to 328.8)	21.8 (-5.69 to 49.3)		
Week 6 (n=108, 100)	110.64 (98 to 123.29)	15.1 (2.33 to 27.87)		
Week 9 (n=69, 67)	71.24 (56.46 to 86.02)	23.23 (8.16 to 38.29)		
Week 12 (n=36, 33)	46.4 (27.14 to 65.66)	30.54 (10.08 to 50.99)		
Prior to delivery (n=104, 94)	74.71 (60.27 to 89.15)	23.93 (8.86 to 39)		

Notes:

[10] - # patients analyzed for each timepoint are reported within the category title.

[11] - # patients analyzed for each timepoint are reported within the category title.

Statistical analyses

Statistical analysis title	Ferritin Change from Baseline: Week 3

Statistical analysis description:

Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 226.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set

Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [12]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	280
Confidence interval	
level	95 %
sides	2-sided
lower limit	241.91
upper limit	318.09

Notes:

[12] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Ferritin Change from Baseline: Week 6

Statistical analysis description:

Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 208.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [13]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	95.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	78.61
upper limit	112.48

Notes:

[13] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Ferritin Change from Baseline: Week 9

Statistical analysis description:

Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 136.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [14]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	48.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	27.76
upper limit	68.27

Notes:

[14] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Ferritin Change from Baseline: Week 12

Statistical analysis description:

Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 69.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.255 [15]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	15.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.73
upper limit	43.46

Notes:

[15] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Ferritin Change from Baseline: Prior to delivery

Statistical analysis description:

Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 198.

Comparison groups	Oral iron - Full analysis set v Ferric carboxymaltose - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [16]
Method	ANCOVA
Parameter estimate	Difference of LSM
Point estimate	50.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	31.39
upper limit	70.17

Notes:

[16] - The significance level is set at a 2-sided alpha of 0.05.

Secondary: Change from Baseline to Week 3, 6, 9, 12 and Last Visit Prior to Delivery

in Serum Iron	
End point title	Change from Baseline to Week 3, 6, 9, 12 and Last Visit Prior to Delivery in Serum Iron

End point description:

Baseline was defined as the last non-missing value prior to dosing including Day 1. Least-Squares-Means means estimates were taken from the repeated measures model for weeks 3, 6, 9 and 12, and from a ANCOVA results model for the last visit prior to delivery.

End point type	Secondary

End point timeframe:

Day 0 (baseline), Weeks 3, 6, 9, 12, last visit prior to delivery (longest is Week 25)

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121[17]	115[18]		
Units: µmol/L				
least squares mean (confidence interval 95%)				
Week 3 (n=117, 111)	7.86 (5.87 to 9.86)	11.63 (9.6 to 13.66)		
Week 6 (n=108, 100)	6.85 (4.89 to 8.81)	10.52 (8.52 to 12.53)		
Week 9 (n=69, 67)	7.38 (4.79 to 9.98)	10.79 (8.11 to 13.46)		
Week 12 (n=36, 33)	4.75 (1.04 to 8.45)	12.56 (8.63 to 16.48)		
Prior to delivery (n=104, 94)	7.08 (4.97 to 9.19)	12.73 (10.53 to 14.93)		

Notes:

[17] - # patients analyzed for each timepoint are reported within the category title.

[18] - # patients analyzed for each timepoint are reported within the category title.

Statistical analyses

Statistical analysis title	Serum Iron Change from Baseline: Week 3

Statistical analysis description:

Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 228.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [19]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	-3.77

Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.5
upper limit	-1.03

Notes:

[19] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Serum Iron Change from Baseline: Week 6

Statistical analysis description:

Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 208.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008 [20]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	-3.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.35
upper limit	-0.99

Notes:

[20] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Serum Iron Change from Baseline: Week 9

Statistical analysis description:

Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 136.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.067 [21]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	-3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.05
upper limit	0.24

Notes:

[21] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Serum Iron Change from Baseline: Week 12

Statistical analysis description:

Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 69.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005 [22]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	-7.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.16
upper limit	-2.46

Notes:

[22] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Serum Iron Change from Baseline: Prior to Delivery

Statistical analysis description:

Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 198.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [23]
Method	ANCOVA
Parameter estimate	Difference of LSM
Point estimate	-5.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.48
upper limit	-2.83

Notes:

[23] - The significance level is set at a 2-sided alpha of 0.05.

Secondary: Change from Baseline to Week 3, 6, 9, 12 and Last Visit Prior to Delivery in Transferrin Saturation (TSAT)

End point title	Change from Baseline to Week 3, 6, 9, 12 and Last Visit Prior to Delivery in Transferrin Saturation (TSAT)

End point description:

TSAT is the ratio of serum iron and total iron-binding capacity, multiplied by 100. Of the transferrin that is available to bind iron, this value tells a clinician how much serum iron are actually bound.
Baseline was defined as the last non-missing value prior to dosing including Day 1. Least-Squares-Means means estimates were taken from the repeated measures model for weeks 3, 6, 9 and 12, and from a ANCOVA results model for the last visit prior to delivery.

End point type	Secondary

End point timeframe:

Day 0 (baseline), Weeks 3, 6, 9, 12, last visit prior to delivery (longest is Week 25)

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121[24]	115[25]		
Units: percentage total iron-binding capacity				
least squares mean (confidence interval 95%)				
Week 3 (n=117, 111)	13.65 (11.18 to 16.11)	14.17 (11.69 to 16.66)		
Week 6 (n=108, 100)	11.48 (9.02 to 13.94)	13.06 (10.55 to 15.57)		
Week 9 (n=69, 67)	10.64 (7.63 to 13.65)	12.93 (9.82 to 16.03)		
Week 12 (n=36, 33)	6.74 (2.28 to 11.2)	16.12 (11.4 to 20.85)		
Prior to delivery (n=104, 94)	10.51 (7.86 to 13.17)	15.44 (12.68 to 18.2)		

Notes:

[24] - # patients analyzed for each timepoint are reported within the category title.

[25] - # patients analyzed for each timepoint are reported within the category title.

Statistical analyses

Statistical analysis title	Transferrin Saturation: Week 3

Statistical analysis description:

Values are change from baseline to timepoint.
Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 228.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.758 [26]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	-0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.89
upper limit	2.84

Notes:

[26] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Transferrin Saturation: Week 6

Statistical analysis description:

Values are change from baseline to timepoint.
Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 208.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.357 [27]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	-1.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.95
upper limit	1.79

Notes:

[27] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Transferrin Saturation: Week 9

Statistical analysis description:

Values are change from baseline to timepoint.
Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 136.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.287 [28]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	-2.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.51
upper limit	1.94

Notes:

[28] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Transferrin Saturation: Week 12

Statistical analysis description:

Values are change from baseline to timepoint.
Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 69.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set

Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005 [29]
Method	Repeated measures model
Parameter estimate	Difference of LSM
Point estimate	-9.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.82
upper limit	-2.95

Notes:

[29] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Transferrin Saturation: Prior to delivery

Statistical analysis description:

Values are change from baseline to timepoint.
Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 198.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [30]
Method	ANCOVA
Parameter estimate	Difference of LSM
Point estimate	-4.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.48
upper limit	-1.38

Notes:

[30] - The significance level is set at a 2-sided alpha of 0.05.

Secondary: Change from Baseline to Week 3, 6, 9 and 12 in Blood Reticulocyte Cell Haemoglobin Content

End point title	Change from Baseline to Week 3, 6, 9 and 12 in Blood Reticulocyte Cell Haemoglobin Content

End point description:

An analysis of haematological and iron parameter change from baseline.
Baseline was defined as the last non-missing value prior to dosing including Day 1. Least-Squares-Means means estimates were taken from the repeated measures model.

End point type	Secondary

End point timeframe:

Day 0 (baseline), Weeks 3, 6, 9, 12

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121[31]	115[32]		
Units: pg				
least squares mean (confidence interval 95%)				
Week 3 (n=114, 108)	3.92 (3.56 to 4.28)	3.04 (2.67 to 3.41)		
Week 6 (n=109, 97)	3.32 (2.97 to 3.68)	3.07 (2.7 to 3.44)		
Week 9 (n=68, 62)	2.99 (2.59 to 3.4)	3.01 (2.59 to 3.43)		
Week 12 (n=34, 32)	2.76 (1.97 to 3.56)	2.86 (2.04 to 3.68)		

Notes:

[31] - # patients analyzed for each timepoint are reported within the category title.

[32] - # patients analyzed for each timepoint are reported within the category title.

Statistical analyses

Statistical analysis title	Reticulocyte Cell Haemoglobin Content: Week 3

Statistical analysis description:

Values are change from baseline to timepoint.
Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 222.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [33]
Method	Repeated measures model
Parameter estimate	Difference in LSM
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	1.37

Notes:

[33] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Reticulocyte Cell Haemoglobin Content: Week 6

Statistical analysis description:

Values are change from baseline to timepoint.
Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 206.

Comparison groups	Oral iron - Full analysis set v Ferric carboxymaltose - Full analysis set

Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.312 [34]
Method	Repeated measures model
Parameter estimate	Difference in LSM
Point estimate	0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.23
upper limit	0.73

Notes:

[34] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Reticulocyte Cell Haemoglobin Content: Week 9

Statistical analysis description:

Values are change from baseline to timepoint.
Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 130.

Comparison groups	Oral iron - Full analysis set v Ferric carboxymaltose - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.968 [35]
Method	Repeated measures model
Parameter estimate	Difference in LSM
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.57
upper limit	0.54

Notes:

[35] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	Reticulocyte Cell Haemoglobin Content: Week 12

Statistical analysis description:

Values are change from baseline to timepoint.
Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 66.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.865 [36]
Method	Repeated measures model
Parameter estimate	Difference in LSM
Point estimate	-0.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.22
upper limit	1.03

Notes:

[36] - The significance level is set at a 2-sided alpha of 0.05.

Secondary: Change from Baseline to Week 3, 6, 9, 12 and Last Visit Prior to Delivery in Soluble Transferrin Receptor (STR)

End point title	Change from Baseline to Week 3, 6, 9, 12 and Last Visit Prior to Delivery in Soluble Transferrin Receptor (STR)

End point description:

Baseline was defined as the last non-missing value prior to dosing including Day 1. Least-Squares-Means estimates were taken from the repeated measures model for weeks 3, 6, 9 and 12, and from a ANCOVA results model for the last visit prior to delivery.

End point type	Secondary

End point timeframe:

Day 0 (baseline), Weeks 3, 6, 9, 12, last visit prior to delivery

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121[37]	115[38]		
Units: mg/L				
least squares mean (confidence interval 95%)				
Week 3 (n=117, 111)	-1.62 (-1.87 to -1.37)	-1.43 (-1.68 to -1.18)		
Week 6 (n=108, 100)	-2.36 (-2.6 to -2.12)	-2.01 (-2.26 to -1.77)		
Week 9 (n=69, 68)	-2.66 (-3.26 to -2.05)	-1.64 (-2.28 to -1.01)		
Week 12 (36, 33)	-2.21 (-4.3 to -0.11)	-0.2 (-2.41 to 2.01)		
Prior to delivery (n=104, 94)	-2.25 (-2.93 to -1.57)	-1.6 (-2.31 to -0.9)		

Notes:

[37] - # patients analyzed for each timepoint are reported within the category title.

[38] - # patients analyzed for each timepoint are reported within the category title.

Statistical analyses

Statistical analysis title	STR: Week 3

Statistical analysis description:

Values are change from baseline to timepoint.
Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 228.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set

Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.254 [39]
Method	Repeating measures model
Parameter estimate	Difference of LSM
Point estimate	-0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.53
upper limit	0.14

Notes:

[39] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	STR: Week 6

Statistical analysis description:

Values are change from baseline to timepoint.
Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 208.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.039 [40]
Method	Repeating measures model
Parameter estimate	Difference of LSM
Point estimate	-0.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.67
upper limit	-0.02

Notes:

[40] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	STR: Week 9

Statistical analysis description:

Values are change from baseline to timepoint.
Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 137.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.023 [41]
Method	Repeating measures model
Parameter estimate	Difference of LSM
Point estimate	-1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.88
upper limit	-0.14

Notes:

[41] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	STR: Week 12

Statistical analysis description:

Values are change from baseline to timepoint.
Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 69.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.192 [42]
Method	Repeating measures model
Parameter estimate	Difference of LSM
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.05
upper limit	1.04

Notes:

[42] - The significance level is set at a 2-sided alpha of 0.05.

Statistical analysis title	STR: Prior to delivery

Statistical analysis description:

Values are change from baseline to timepoint.
Difference is calculated as FCM parameter level minus oral iron parameter levels. Thus a positive difference indicates a higher parameter level in the FCM arm. Subjects in this analysis is 198.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.161 [43]
Method	ANCOVA
Parameter estimate	Difference of LSM
Point estimate	-0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.55
upper limit	0.26

Notes:

[43] - The significance level is set at a 2-sided alpha of 0.05.

Secondary: Percentage of Subjects Achieving Anaemia Correction

End point title	Percentage of Subjects Achieving Anaemia Correction

End point description:

Anaemia correction is used as a measure of treatment response and is defined as achievement of Hb ≥11.0 g/dL at any time before delivery. Any subject with an Hb level of ≥11.0 g/dL at baseline was regarded as a non-responder. For a subject without a baseline Hb level, no response was defined.

End point type	Secondary

End point timeframe:

Day 0 to last visit prior to delivery (longest is Week 25)

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121	115		
Units: percentage of total subjects				
number (not applicable)				
With anaemia correction	83.5	70.2		
Without anaemia correction	16.5	29.8		

Statistical analyses

Statistical analysis title	Anaemia correction

Statistical analysis description:

p-value is from a logistic regression model with fixed factors for treatment and pooled country and a covariate for baseline Hb level. The treatment odds ratio (OR) is the FCM odds divided by the oral iron odds.

Comparison groups	Oral iron - Full analysis set v Ferric carboxymaltose - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.031 [44]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.07
upper limit	3.97

Notes:

[44] - The significance level is set at a 2-sided alpha of 0.05.

Secondary: Kaplan-Meier Estimate for Time to Anaemia Correction

End point title	Kaplan-Meier Estimate for Time to Anaemia Correction

End point description:

Subjects have their times censored at their last on study assessment considered for analysis if they have not corrected by that time.
Subjects with a baseline Hb level of at least 11 g/dL or no post-baseline assessments are censored with a time to anaemia correction of day 1.

End point type	Secondary

End point timeframe:

Day 0 to last visit prior to delivery (longest is Week 25)

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121	115		
Units: weeks				
median (confidence interval 95%)	3.4 (2.9 to 4.4)	4.3 (3.4 to 5)		

Statistical analyses

Statistical analysis title	Time to Anaemia Correction

Statistical analysis description:

p-value based on an unstratified log-rank test.

Comparison groups	Ferric carboxymaltose - Full analysis set v Oral iron - Full analysis set
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.11 [45]
Method	Logrank

Notes:

[45] - The significance level is set at a 2-sided alpha of 0.05.

Secondary: Change from Baseline to Week 3 in Health-Related Quality of Life (QoL) Using the 36-item Short-Form Health Survey (SF-36)

End point title	Change from Baseline to Week 3 in Health-Related Quality of Life (QoL) Using the 36-item Short-Form Health Survey (SF-36)

End point description:

SF-36 is a generic 36-item questionnaire measuring health-related quality of life (HRQoL) covering 2 summary measures: physical component summary (PCS) and mental component summary (MCS). The PCS has 4 subscales: physical function, role limitations due to physical problems, pain, and general health perception. The MCS also has 4 subscales: vitality, social function, role limitations due to emotional problems, and mental health. Participants self-report on each subscale that have between 2-6 choices per item using Likert-type responses (e.g. none of the time, some of the time, etc.).
Summations of item scores for each subscale are transformed into a range from 0 to 100; zero= worst HRQoL, 100=best HRQoL. PCS and MCS scores are constructed as a T-score with a mean of 50 and standard deviation of 10 and no minimum or maximum score; higher scores indicate better health status.
Positive change from baseline values represent improved HRQoL.

End point type	Secondary

End point timeframe:

Day 0 (baseline), Week 3

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121	115		
Units: units on a scale				
arithmetic mean (standard deviation)				
Physical Component Summary	-0.61 (± 6.393)	-1.18 (± 6.873)		
Physical functioning	-2.37 (± 20.524)	-3.48 (± 21.201)		
Role limits due to physical	0.27 (± 23.147)	-2.57 (± 22.142)		
Bodily pain	-1.65 (± 22.221)	-3.04 (± 16.558)		
General health perception	2.07 (± 12)	1.21 (± 12.699)		
Mental Component Summary	2.18 (± 8.655)	1.34 (± 8.386)		
Vitality	6.3 (± 19.705)	3.96 (± 19.693)		
Social Functioning	3.5 (± 22.102)	0.56 (± 19.667)		
Role limits due to emotional	1.45 (± 23.186)	-1.08 (± 20.637)		
Mental health	1.65 (± 14.082)	1.79 (± 13.37)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Last Visit Before Delivery in Health-Related Quality of Life (HRQoL) Using the 36-item Short-Form Health Survey (SF-36)

End point title	Change from Baseline to Last Visit Before Delivery in Health-Related Quality of Life (HRQoL) Using the 36-item Short-Form Health Survey (SF-36)

End point description:

SF-36 is a generic 36-item questionnaire measuring health-related quality of life (HRQoL) covering 2 summary measures: physical component summary (PCS) and mental component summary (MCS). The PCS has 4 subscales: physical function, role limitations due to physical problems, pain, and general health perception. The MCS also has 4 subscales: vitality, social function, role limitations due to emotional problems, and mental health. Participants self-report on each subscale that have between 2-6 choices per item using Likert-type responses (e.g. none of the time, some of the time, etc.). Summations of item scores for each subscale are transformed into a range from 0 to 100; zero= worst HRQoL, 100=best HRQoL. PCS and MCS scores are constructed as a T-score with a mean of 50 and standard deviation of 10 and no minimum or maximum score; higher scores indicate better health status.
Positive change from baseline values represent improved HRQoL.

End point type	Secondary

End point timeframe:

Day 0 (baseline), Last Visit Before Delivery (longest is Week 25)

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121	115		
Units: units on a scale				
arithmetic mean (standard deviation)				
Physical Component Summary	-2.74 (± 7.566)	-3.88 (± 7.905)		
Physical functioning	-9.42 (± 23.609)	-12.59 (± 22.036)		
Role limits due to physical	-5.66 (± 25.787)	-11.4 (± 25.909)		
Bodily pain	-3.21 (± 23.203)	-6.43 (± 24.096)		
General health perception	1.76 (± 13.114)	0.74 (± 12.674)		
Mental Component Summary	2.37 (± 9.059)	0.78 (± 9.758)		
Vitality	6.51 (± 21.897)	2.34 (± 22.089)		
Social Functioning	3.03 (± 23.613)	-2.5 (± 24.553)		
Role limits due to emotional	-1.68 (± 24.611)	-5.52 (± 26.82)		
Mental health	1.74 (± 15.312)	-0.13 (± 16.649)		

Statistical analyses

No statistical analyses for this end point

Secondary: Patient Global Assessment at Baseline

End point title	Patient Global Assessment at Baseline

End point description:

Self-reported patient global assessment (PGA) was rated on a scale of 1-7: Score 1 = Has much improved, 2 = Has (moderately) improved, 3 = Has little improved, 4 = Is unchanged, 5 = Is a little worse, 6 = Is (moderately) worse, 7 = Is much worse.

Percentage was calculated using the Full Analysis Set population as the denominator: FCM = 121 patients and Oral Iron = 115 patients. When fewer patients completed the global assessment at any timepoint, the sum of the percentages across the global assessment scores will be less than 100%.

End point type	Secondary

End point timeframe:

Day 0 (baseline)

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121	115		
Units: percentage of patients				
number (not applicable)				
Score 1	1.7	0.9		
Score 2	0.8	1.7		
Score 3	5.8	2.6		
Score 4	81.8	89.6		
Score 5	9.1	3.5		
Score 6	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Patient Global Assessment at Week 3

End point title	Patient Global Assessment at Week 3

End point description:

Self-reported patient global assessment (PGA) was rated on a scale of 1-7: Score 1 = Has much improved, 2 = Has (moderately) improved, 3 = Has little improved, 4 = Is unchanged, 5 = Is a little worse, 6 = Is (moderately) worse, 7 = Is much worse.

Percentage was calculated using the Full Analysis Set population as the denominator: FCM = 121 patients and Oral Iron = 115 patients. When fewer patients completed the global assessment at any timepoint, the sum of the percentages across the global assessment scores will be less than 100%.

End point type	Secondary

End point timeframe:

Week 3

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121	115		
Units: percentage of patients				
number (not applicable)				
Score 1	16.5	12.2		
Score 2	19.8	18.3		
Score 3	35.5	31.3		
Score 4	24.8	34.8		
Score 5	0	0.9		
Score 6	0.8	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Patient Global Assessment at Week 6

End point title	Patient Global Assessment at Week 6

End point description:

Self-reported patient global assessment (PGA) was rated on a scale of 1-7: Score 1 = Has much improved, 2 = Has (moderately) improved, 3 = Has little improved, 4 = Is unchanged, 5 = Is a little worse, 6 = Is (moderately) worse, 7 = Is much worse.

Percentage was calculated using the Full Analysis Set population as the denominator: FCM = 121 patients and Oral Iron = 115 patients. When fewer patients completed the global assessment at any timepoint, the sum of the percentages across the global assessment scores will be less than 100%.

End point type	Secondary

End point timeframe:

Week 6

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121	115		
Units: percentage of patients				
number (not applicable)				
Score 1	24	17.4		
Score 2	24.8	23.5		
Score 3	28.9	30.4		
Score 4	9.9	14.8		
Score 5	1.7	0.9		
Score 6	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Patient Global Assessment at Week 9

End point title	Patient Global Assessment at Week 9

End point description:

Self-reported patient global assessment (PGA) was rated on a scale of 1-7: Score 1 = Has much improved, 2 = Has (moderately) improved, 3 = Has little improved, 4 = Is unchanged, 5 = Is a little worse, 6 = Is (moderately) worse, 7 = Is much worse.

Percentage was calculated using the Full Analysis Set population as the denominator: FCM = 121 patients and Oral Iron = 115 patients. When fewer patients completed the global assessment at any timepoint, the sum of the percentages across the global assessment scores will be less than 100%.

End point type	Secondary

End point timeframe:

Week 9

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121	115		
Units: percentage of patients				
number (not applicable)				
Score 1	14	17.4		
Score 2	16.5	17.4		
Score 3	15.7	16.5		
Score 4	11.6	6.1		
Score 5	0	0		
Score 6	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Patient Global Assessment at Week 12

End point title	Patient Global Assessment at Week 12

End point description:

Self-reported patient global assessment (PGA) was rated on a scale of 1-7: Score 1 = Has much improved, 2 = Has (moderately) improved, 3 = Has little improved, 4 = Is unchanged, 5 = Is a little worse, 6 = Is (moderately) worse, 7 = Is much worse.

Percentage was calculated using the Full Analysis Set population as the denominator: FCM = 121 patients and Oral Iron = 115 patients. When fewer patients completed the global assessment at any timepoint, the sum of the percentages across the global assessment scores will be less than 100%.

End point type	Secondary

End point timeframe:

Week 12

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121	115		
Units: percentage of patients				
number (not applicable)				
Score 1	9.1	8.7		
Score 2	6.6	11.3		
Score 3	11.6	3.5		
Score 4	2.5	2.6		
Score 5	0	1.7		
Score 6	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Patient Global Assessment at Last Visit Prior to Delivery

End point title	Patient Global Assessment at Last Visit Prior to Delivery

End point description:

Self-reported patient global assessment (PGA) was rated on a scale of 1-7: Score 1 = Has much improved, 2 = Has (moderately) improved, 3 = Has little improved, 4 = Is unchanged, 5 = Is a little worse, 6 = Is (moderately) worse, 7 = Is much worse.

Percentage was calculated using the Full Analysis Set population as the denominator: FCM = 121 patients and Oral Iron = 115 patients. When fewer patients completed the global assessment at any timepoint, the sum of the percentages across the global assessment scores will be less than 100%.

End point type	Secondary

End point timeframe:

Last Visit Before Delivery (longest is week 25)

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121	115		
Units: percentage of patients				
number (not applicable)				
Score 1	23.1	24.3		
Score 2	23.1	19.1		
Score 3	28.1	26.1		
Score 4	11.6	8.7		
Score 5	0.8	2.6		
Score 6	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Patient Global Assessment Following Delivery

End point title	Patient Global Assessment Following Delivery

End point description:

Self-reported patient global assessment (PGA) was rated on a scale of 1-7: Score 1 = Has much improved, 2 = Has (moderately) improved, 3 = Has little improved, 4 = Is unchanged, 5 = Is a little worse, 6 = Is (moderately) worse, 7 = Is much worse.

Percentage was calculated using the Full Analysis Set population as the denominator: FCM = 121 patients and Oral Iron = 115 patients. When fewer patients completed the global assessment at any timepoint, the sum of the percentages across the global assessment scores will be less than 100%.

End point type	Secondary

End point timeframe:

Delivery (longest is week 25)

End point values	Ferric carboxymaltose - Full analysis set	Oral iron - Full analysis set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121	115		
Units: percentage of patients				
number (not applicable)				
Score 1	0	0.9		
Score 2	1.7	1.7		
Score 3	0.8	4.3		
Score 4	0	2.6		
Score 5	0	0		
Score 6	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Newborn Appearance, Pulse, Grimace, Activity, Respiration (APGAR) Scores at 1 minute, 5 minutes and 10 minutes after Birth

End point title	Newborn Appearance, Pulse, Grimace, Activity, Respiration (APGAR) Scores at 1 minute, 5 minutes and 10 minutes after Birth

End point description:

APGAR is a test performed by a healthcare professional at 1, 5 and 10 minutes after birth. The 1-minute score determines how well the baby tolerated the birthing process; the 5- and 10-minute scores assess how well the newborn is adapting to the new environment. The health care provider examines the baby's breathing effort, heart rate, muscle tone, reflexes, and skin color. Each category is scored with 0 (worst score), 1, or 2 (best score), depending on the observed condition. The rating is based on a total score of 1-10, with 10 suggesting the healthiest infant.

End point type	Secondary

End point timeframe:

1-10 minutes after delivery (longest is week 25)

End point values	Ferric carboxymaltose	Oral iron		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	112[46]	109[47]		
Units: units on a scale				
arithmetic mean (standard deviation)				
One minute (n=43, 30)	8.4 (± 0.85)	8.2 (± 1.27)		
Five minutes (n=63, 73)	9.2 (± 0.65)	9 (± 0.79)		
Ten minutes (n=3, 3)	10 (± 0)	10 (± 0)		

Notes:

[46] - Subjects with information about newborns.
newborns are reported within the category line.
[47] - Subjects with information about newborns.
newborns are reported within the category line.

Statistical analyses

No statistical analyses for this end point

Secondary: Newborn Birth Weight

End point title	Newborn Birth Weight

End point description:

End point type	Secondary

End point timeframe:

After delivery (longest is week 25)

End point values	Ferric carboxymaltose	Oral iron		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	109[48]	106[49]		
Units: kg				
arithmetic mean (standard deviation)	3.401 (± 0.4975)	3.384 (± 0.5103)		

Notes:

[48] - Newborns with assessments.

[49] - Newborns with assessments.

Statistical analyses

No statistical analyses for this end point

Secondary: Newborn Cord Serum Ferritin

End point title	Newborn Cord Serum Ferritin

End point description:

End point type	Secondary

End point timeframe:

After delivery (longest is week 25)

End point values	Ferric carboxymaltose	Oral iron		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	85[50]	67[51]		
Units: mcg/L				
arithmetic mean (standard deviation)	255.55 (± 187.189)	236.72 (± 135.927)		

Notes:

[50] - # newborns with assessment

[51] - # newborns with assessment

Statistical analyses

No statistical analyses for this end point

Secondary: Difference in Serum Ferritin Lab Values Between Mother and Newborn

End point title	Difference in Serum Ferritin Lab Values Between Mother and Newborn

End point description:

The difference between newborn and mother lab parameter levels were calculated as the mother’s assessment minus the newborn’s assessment.

End point type	Secondary

End point timeframe:

After delivery (longest is week 25)

End point values	Ferric carboxymaltose	Oral iron		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83[52]	67[53]		
Units: mcg/L				
arithmetic mean (standard deviation)	-173.4 (± 195.017)	-195.15 (± 123.242)		

Notes:

[52] - # mothers and their newborns with assessment

[53] - # mothers and their newborns with assessment

Statistical analyses

No statistical analyses for this end point

Secondary: Participants with Treatment-Emergent Adverse Events (TEAE)

End point title	Participants with Treatment-Emergent Adverse Events (TEAE)

End point description:

An adverse event (AE) is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the administration, at any dose, of a medicinal or therapeutic product whether or not considered related to that product. Relation to study drug was assessed by the investigator. Severity was rated by the investigator on a scale of 1 (mild) to 3 (severe - defined as incapacitating and the subject is unable to work or complete usual activity) Serious AEs include death (death due to progressive disease were not reported as an SAE), a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, a congenital anomaly or birth defect, OR an important medical event that jeopardized the patient and required medical intervention to prevent the previously listed serious outcomes.

AEs in the newborns are not considered treatment-emergent.

End point type	Secondary

End point timeframe:

Day 0 (post treatment) up to 30 days after delivery (longest time is Week 29)

End point values	Ferric carboxymaltose - Safety set	Oral Iron - Safety set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	123	124		
Units: participants				
Any TEAE	60	50		
Related TEAE	14	19		
Severe, related TEAE	0	1		
TEAE with outcome of death	0	0		
Serious TEAE	23	10		
Related, serious TEAE	1	0		
TEAE leading to discontinuation	1	7		
Related TEAE leading to discontinuation	1	6		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Day 0 (post treatment) up to 30 days after delivery (longest time is Week 29)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	16.1

Reporting groups	
Reporting group title	Ferric carboxymaltose - Safety set
Reporting group description:	
Subjects randomized to the ferric carboxymaltose (FCM) treatment arm who received at least 1 dose of randomised treatment.	
Reporting group title	Oral Iron - Safety set
Reporting group description:	
Subjects randomized to the oral iron treatment arm who received at least 1 dose of randomized treatment.	
Reporting group title	Ferric carboxymaltose - Newborns
Reporting group description:	
Adverse events in the newborn of mothers who took ferric carboxymaltose. The reporting group is limited to subjects with information about newborns.	
Reporting group title	Oral iron - Newborns
Reporting group description:	
Adverse events in the newborn of mothers who took oral iron. The reporting group is limited to subjects with information about newborns.	

Serious adverse events	Ferric carboxymaltose - Safety set	Oral Iron - Safety set	Ferric carboxymaltose - Newborns
Total subjects affected by serious adverse events			
subjects affected / exposed	23 / 123 (18.70%)	10 / 124 (8.06%)	6 / 123 (4.88%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Road traffic accident			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Congenital foot malformation			

subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Failed trial of labour			
subjects affected / exposed	2 / 123 (1.63%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal distress syndrome	Additional description: Event was incorrectly assigned to mother rather than newborn.		
subjects affected / exposed	2 / 123 (1.63%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature delivery			
subjects affected / exposed	2 / 123 (1.63%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature rupture of membranes			
subjects affected / exposed	2 / 123 (1.63%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Threatened labour			
subjects affected / exposed	2 / 123 (1.63%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature labour			
subjects affected / exposed	1 / 123 (0.81%)	3 / 124 (2.42%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cephalo-pelvic disproportion			
subjects affected / exposed	1 / 123 (0.81%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix dystocia			

subjects affected / exposed	1 / 123 (0.81%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breech presentation			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical incompetence			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failed induction of labour			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
High risk pregnancy			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine contractions during pregnancy			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine hypotonus			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta			

subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolonged labour			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolonged rupture of membranes			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	3 / 123 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neonatal aspiration			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal asphyxia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental disorder			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Amniotic cavity infection			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Oral iron - Newborns		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 124 (4.03%)		
number of deaths (all causes)	0		

number of deaths resulting from adverse events	0			
Injury, poisoning and procedural complications				
Road traffic accident				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Congenital foot malformation				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pregnancy, puerperium and perinatal conditions				
Failed trial of labour				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foetal distress syndrome	Additional description: Event was incorrectly assigned to mother rather than newborn.			
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Premature delivery				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Premature rupture of membranes				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Threatened labour				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Premature labour				

subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cephalo-pelvic disproportion				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervix dystocia				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breech presentation				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical incompetence				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Failed induction of labour				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
High risk pregnancy				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine contractions during pregnancy				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine hypotonus				

subjects affected / exposed	0 / 124 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pre-eclampsia			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Premature separation of placenta			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prolonged labour			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prolonged rupture of membranes			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Premature baby			
subjects affected / exposed	2 / 124 (1.61%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			

Bronchospasm				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neonatal aspiration				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neonatal asphyxia				
subjects affected / exposed	1 / 124 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neonatal respiratory distress syndrome				
subjects affected / exposed	1 / 124 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	1 / 124 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Mental disorder				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Amniotic cavity infection				
subjects affected / exposed	0 / 124 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Pyelonephritis			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Ferric carboxymaltose - Safety set	Oral Iron - Safety set	Ferric carboxymaltose - Newborns
Total subjects affected by non-serious adverse events			
subjects affected / exposed	50 / 123 (40.65%)	46 / 124 (37.10%)	10 / 123 (8.13%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign lymph node neoplasm			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	0	0	0
Anogenital warts			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Peripheral vascular disorder			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Varicose vein			
subjects affected / exposed	1 / 123 (0.81%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	1	1	0
Pregnancy, puerperium and perinatal conditions			
Meconium stain			
subjects affected / exposed	2 / 123 (1.63%)	0 / 124 (0.00%)	3 / 123 (2.44%)
occurrences (all)	2	0	3
Polyhydramnios			

subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Umbilical cord abnormality			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	1 / 123 (0.81%)
occurrences (all)	0	0	1
Failed induction of labour			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Foetal growth restriction			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Gestational diabetes			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Intrapartum haemorrhage			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Large for dates baby			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Oligohydramnios			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Placental insufficiency			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Postpartum haemorrhage			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Premature labour			
subjects affected / exposed	2 / 123 (1.63%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	2	0	0
Premature rupture of membranes			
subjects affected / exposed	3 / 123 (2.44%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	3	0	0
Uterine contractions during			

pregnancy			
subjects affected / exposed	1 / 123 (0.81%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	1	1	0
Uterine hypotonus			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 123 (0.81%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	1	1	0
Chills			
subjects affected / exposed	1 / 123 (0.81%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	1	1	0
Fatigue			
subjects affected / exposed	4 / 123 (3.25%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	4	0	0
Generalised oedema			
subjects affected / exposed	1 / 123 (0.81%)	2 / 124 (1.61%)	0 / 123 (0.00%)
occurrences (all)	1	2	0
Hyperthermia			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Local swelling			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	2 / 123 (1.63%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	2	0	0
Pyrexia			
subjects affected / exposed	3 / 123 (2.44%)	2 / 124 (1.61%)	0 / 123 (0.00%)
occurrences (all)	3	2	0
Suprapubic pain			

subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Haemorrhagic ovarian cyst			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Pelvic pain			
subjects affected / exposed	3 / 123 (2.44%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	3	0	0
Vaginal discharge			
subjects affected / exposed	4 / 123 (3.25%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	4	1	0
Vaginal haemorrhage			
subjects affected / exposed	1 / 123 (0.81%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	1	1	0
Vaginal odour			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal pain			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal pruritus			
subjects affected / exposed	1 / 123 (0.81%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	1	1	0
Respiratory, thoracic and mediastinal disorders			
Nasal flaring			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	1 / 123 (0.81%)
occurrences (all)	0	0	1
Tachypnoea			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	0	0	0
Use of accessory respiratory muscles			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	1 / 123 (0.81%)
occurrences (all)	0	0	1
Cough			

subjects affected / exposed	2 / 123 (1.63%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	2	1	0
Dyspnoea			
subjects affected / exposed	1 / 123 (0.81%)	3 / 124 (2.42%)	0 / 123 (0.00%)
occurrences (all)	1	3	0
Nasal discharge discolouration			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	2 / 123 (1.63%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 123 (0.81%)	2 / 124 (1.61%)	0 / 123 (0.00%)
occurrences (all)	1	2	0
Sleep disorder			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Investigations			
Amniotic fluid volume decreased			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Blood pressure increased			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Gastric pH decreased			
subjects affected / exposed	1 / 123 (0.81%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	1	1	0
Haemoglobin decreased			

subjects affected / exposed	0 / 123 (0.00%)	2 / 124 (1.61%)	0 / 123 (0.00%)
occurrences (all)	0	2	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	1 / 123 (0.81%)
occurrences (all)	0	0	1
Lip injury			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	1 / 123 (0.81%)
occurrences (all)	0	0	1
Perineal injury			
subjects affected / exposed	2 / 123 (1.63%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	4	0	0
Uterine cervical laceration			
subjects affected / exposed	2 / 123 (1.63%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	2	0	0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	0	0	0
Single umbilical artery			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Bradycardia foetal			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Supraventricular extrasystoles			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	10 / 123 (8.13%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	10	1	0
Dizziness			
subjects affected / exposed	5 / 123 (4.07%)	2 / 124 (1.61%)	0 / 123 (0.00%)
occurrences (all)	5	2	0

Dysgeusia			
subjects affected / exposed	2 / 123 (1.63%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	2	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Haemorrhagic anaemia			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	2 / 123 (1.63%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	2	0	0
Eye disorders			
Eye discharge			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Visual impairment			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	7 / 123 (5.69%)	6 / 124 (4.84%)	0 / 123 (0.00%)
occurrences (all)	8	7	0
Dyspepsia			
subjects affected / exposed	1 / 123 (0.81%)	8 / 124 (6.45%)	0 / 123 (0.00%)
occurrences (all)	1	8	0

Abdominal pain			
subjects affected / exposed	3 / 123 (2.44%)	2 / 124 (1.61%)	0 / 123 (0.00%)
occurrences (all)	3	2	0
Abdominal pain lower			
subjects affected / exposed	2 / 123 (1.63%)	2 / 124 (1.61%)	0 / 123 (0.00%)
occurrences (all)	2	2	0
Abdominal pain upper			
subjects affected / exposed	1 / 123 (0.81%)	6 / 124 (4.84%)	0 / 123 (0.00%)
occurrences (all)	1	7	0
Constipation			
subjects affected / exposed	2 / 123 (1.63%)	6 / 124 (4.84%)	0 / 123 (0.00%)
occurrences (all)	2	7	0
Diarrhoea			
subjects affected / exposed	2 / 123 (1.63%)	4 / 124 (3.23%)	0 / 123 (0.00%)
occurrences (all)	2	4	0
Gastritis			
subjects affected / exposed	2 / 123 (1.63%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	2	1	0
Melaena			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	2 / 123 (1.63%)	3 / 124 (2.42%)	0 / 123 (0.00%)
occurrences (all)	2	3	0
Hepatobiliary disorders			
Liver disorder			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Skin discolouration			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	1 / 123 (0.81%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	1 / 123 (0.81%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	1	1	0
Pruritus generalised			

subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Pyelocaliectasis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 124 (0.00%)	1 / 123 (0.81%)
occurrences (all)	0	0	1
Endocrine disorders			
Autoimmune thyroiditis			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Hypothyroidism			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 123 (1.63%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	2	0	0
Back pain			
subjects affected / exposed	3 / 123 (2.44%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	3	1	0
Flank pain			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Ligament pain			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			

subjects affected / exposed	2 / 123 (1.63%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Tenosynovitis stenosans			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Candida infection			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	1 / 123 (0.81%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	1	1	0
Gastroenteritis			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Herpes virus infection			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	2 / 123 (1.63%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	2	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0

Tinea cruris			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	4 / 123 (3.25%)	4 / 124 (3.23%)	0 / 123 (0.00%)
occurrences (all)	7	4	0
Urinary tract infection			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection bacterial			
subjects affected / exposed	1 / 123 (0.81%)	0 / 124 (0.00%)	0 / 123 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 123 (0.00%)	1 / 124 (0.81%)	0 / 123 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Oral iron - Newborns		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 124 (4.84%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign lymph node neoplasm			
subjects affected / exposed	1 / 124 (0.81%)		
occurrences (all)	1		
Anogenital warts			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Peripheral vascular disorder			
subjects affected / exposed	1 / 124 (0.81%)		
occurrences (all)	1		
Flushing			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Varicose vein			

subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Pregnancy, puerperium and perinatal conditions			
Meconium stain			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Polyhydramnios			
subjects affected / exposed	1 / 124 (0.81%)		
occurrences (all)	1		
Umbilical cord abnormality			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Failed induction of labour			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Foetal growth restriction			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Gestational diabetes			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Intrapartum haemorrhage			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Large for dates baby			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Oligohydramnios			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Placental insufficiency			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Postpartum haemorrhage			

subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Premature labour			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Premature rupture of membranes			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Uterine contractions during pregnancy			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Uterine hypotonus			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Generalised oedema			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Hyperthermia			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Local swelling			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Oedema			

subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Suprapubic pain			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Pelvic pain			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Vaginal discharge			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Vaginal haemorrhage			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Vaginal odour			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Vulvovaginal pain			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Vulvovaginal pruritus			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			

Nasal flaring			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Tachypnoea			
subjects affected / exposed	1 / 124 (0.81%)		
occurrences (all)	1		
Use of accessory respiratory muscles			
subjects affected / exposed	1 / 124 (0.81%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Nasal discharge discolouration			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Productive cough			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Investigations			

Amniotic fluid volume decreased subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Blood pressure increased subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Gastric pH decreased subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Haemoglobin decreased subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Lip injury subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Perineal injury subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Uterine cervical laceration subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Congenital, familial and genetic disorders Hydrocele subjects affected / exposed occurrences (all)	1 / 124 (0.81%) 1		
Single umbilical artery subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Cardiac disorders Bradycardia foetal subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		

Supraventricular extrasystoles subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Nervous system disorders Headache subjects affected / exposed occurrences (all) Dizziness subjects affected / exposed occurrences (all) Dysgeusia subjects affected / exposed occurrences (all) Hypoaesthesia subjects affected / exposed occurrences (all) Sciatica subjects affected / exposed occurrences (all) Syncope subjects affected / exposed occurrences (all)	 0 / 124 (0.00%) 0 0 / 124 (0.00%) 0 0 / 124 (0.00%) 0 0 / 124 (0.00%) 0 0 / 124 (0.00%) 0 0 / 124 (0.00%) 0		
Blood and lymphatic system disorders Haemorrhagic anaemia subjects affected / exposed occurrences (all)	 0 / 124 (0.00%) 0		
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	 0 / 124 (0.00%) 0		
Eye disorders Eye discharge subjects affected / exposed occurrences (all) Ocular hyperaemia subjects affected / exposed occurrences (all)	 0 / 124 (0.00%) 0 0 / 124 (0.00%) 0		

Visual impairment subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Dyspepsia subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Abdominal pain subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Constipation subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Diarrhoea subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Gastritis subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Melaena subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Vomiting subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Hepatobiliary disorders			

Liver disorder subjects affected / exposed occurrences (all)	0 / 124 (0.00%) 0		
Skin and subcutaneous tissue disorders Skin discolouration subjects affected / exposed occurrences (all) Pruritus subjects affected / exposed occurrences (all) Pruritus generalised subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all)	 0 / 124 (0.00%) 0 0 / 124 (0.00%) 0 0 / 124 (0.00%) 0 0 / 124 (0.00%) 0		
Renal and urinary disorders Pyelocaliectasis subjects affected / exposed occurrences (all)	 0 / 124 (0.00%) 0		
Endocrine disorders Autoimmune thyroiditis subjects affected / exposed occurrences (all) Hypothyroidism subjects affected / exposed occurrences (all)	 0 / 124 (0.00%) 0 0 / 124 (0.00%) 0		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Flank pain	 0 / 124 (0.00%) 0 0 / 124 (0.00%) 0 		

subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Joint swelling			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Ligament pain			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Musculoskeletal stiffness			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Neck pain			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Tenosynovitis stenosans			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Candida infection			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Herpes virus infection			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		

Influenza			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Tinea cruris			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Urinary tract infection bacterial			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 124 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 June 2011	- Change of Inclusion Criterion 1 to allow inclusion of pregnant women from gestational Week 16 to Week 33 at baseline visit. - Change of Inclusion Criterion 2 to align inclusion Hb concentration for second and third trimester to align with Centers for Disease Control and Prevention guidelines. - Amended the statistical method for interim analysis. - Increased the number of sites from 25 to 40, and the site locations were changed from Germany, Saudi Arabia, Sweden, Switzerland and Turkey to Western Europe, Middle East, Asia Pacific and Russia. - Administrative changes to ensure consistency between protocol sections and synopsis, clarify the definition of previous iron therapy (Exclusion Criteria #1), clarify the required number of subjects for the interim analysis, and correct a calculation error in the document.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported