



Clinical trial results:

Randomized double-blind explorative controlled clinical trial analyzing the effects of ferric carboxymaltose in patients with iron deficiency and chronic heart failure

Summary

EudraCT number	2019-003858-85
Trial protocol	AT
Global end of trial date	14 December 2021

Results information

Result version number	v1 (current)
This version publication date	11 October 2022
First version publication date	11 October 2022

Trial information

Trial identification

Sponsor protocol code	HFIRONT
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University Innsbruck
Sponsor organisation address	Christoph-Probst-Platz 1, Innrain 52, Innsbruck, Austria, 6020
Public contact	Univ. Prof. Dr. Günther Weiss, Medical University Innsbruck, Department of Internal Medicine II, Anichstrasse 35, 6020 IBK, 0043 0512504 23251, guenter.weiss@i-med.ac.at
Scientific contact	Univ. Prof. Dr. Günther Weiss, Medical University Innsbruck, Department of Internal Medicine II, Anichstrasse 35, 6020 IBK, 0043 0512504 23251, guenter.weiss@i-med.ac.at

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	14 December 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 December 2021
Global end of trial reached?	Yes
Global end of trial date	14 December 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Primary objective of this study is to identify the mechanism(s) underlying the beneficial effects of iron supplementation in iron-deficient patients with CHF.

Protection of trial subjects:

Administration of intravenous iron is considered a safe procedure, but severe hypersensitivity reactions (HSRs) can occur at a very low frequency. However, the frequency of such HSR is less than 0,01 % and comparable with administration of paracetamol or ibuprofen.

Background therapy:

Patients should be on optimized background therapy according to the ESC guidelines 2016 for the diagnosis and treatment of acute and chronic heart failure. Changes or improvement in heart failure medication – if needed – are allowed throughout the study period except for the additional administration of iron preparation. Individually optimized long-term treatment will be recorded as well as relevant concomitant medication, which is intended to treat AEs.

No other investigational product is allowed to be used concomitantly with the study treatment. The patient must not have been administered another investigational product within 30 days before the baseline visit.

Evidence for comparator:

There is no evidence for comparators

Actual start date of recruitment	02 January 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 2
Worldwide total number of subjects	2
EEA total number of subjects	2

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	2
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Candidates for the study will be screened during their scheduled visits at the cardiology ambulance for chronic heart failure (CHF) and concomitant iron deficiency (ID). If the patient meets all the inclusion criteria and none of the exclusion criteria, a baseline visit will be arranged.

Pre-assignment

Screening details:

Candidates for the study will be screened during their scheduled visits at the cardiology ambulance for chronic heart failure (CHF) and concomitant iron deficiency (ID).

Period 1

Period 1 title	Treatment (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Randomization will be done by an independent expert at the Institute of Medical Statistics and Informatics applying the permuted block method.

Arms

Are arms mutually exclusive?	Yes
Arm title	Ferric carboxymaltose
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Ferric Carboxymaltose
Investigational medicinal product code	
Other name	Ferinject
Pharmaceutical forms	Concentrate and solvent for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1000 mg of ferric carboxymaltose (Ferinject®) will be given in 50 mL sterile sodium chloride 0.9 % via perfusor over a period of 60 minutes. It will be provided by the dispensary of the Innsbruck University Hospital in a black perfusor syringe and will be administered via a black perfusion line.

Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Sodiumchloride 0,9%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sodium chloride 0.9% will be given via a perfusor over 60 minutes. It will be provided by the dispensary of the Innsbruck University Hospital in a black perfusor syringe and will be administered via a black perfusion line.

Number of subjects in period 1	Ferric carboxymaltose	Placebo
Started	1	1
Completed	1	0
Not completed	0	1
Adverse event, serious fatal	-	1

Baseline characteristics

Reporting groups

Reporting group title	Treatment
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Reporting group description: -

Reporting group values	Treatment	Total	
Number of subjects	2	2	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	2	2	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	56.5		
full range (min-max)	54 to 59	-	
Gender categorical			
Units: Subjects			
Female	0	0	
Male	2	2	

End points

End points reporting groups

Reporting group title	Ferric carboxymaltose
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: Blood count

End point title	Blood count ^[1]
End point description: We will determine the effects of a single ferric carboxymaltose infusion as compared to placebo administration on blood count including reticulocyte count and reticulocyte hemoglobin content.	
End point type	Primary
End point timeframe: Screening - follow-up visit 2	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As only one patient finished this trial no statistical analysis was done.

End point values	Ferric carboxymaltose	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[2]	1 ^[3]		
Units: cell number				
number (not applicable)		99999		

Notes:

[2] - Patient dropped out of study before end of trial

[3] - "99999" is a value for 0 as no analysis was done

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

02.01.2020-14.12.2021

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	5.0
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Reporting groups

Reporting group title	Ferric carboxymaltose
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Reporting group description: -

Reporting group title	Placebo
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Reporting group description: -

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: Only two patients were enrolled in this trial. No Adverse Event was observed.

Serious adverse events	Ferric carboxymaltose	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events	0	1	
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	

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

Non-serious adverse events	Ferric carboxymaltose	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 March 2020	Change from paper-based CRF to electronic CRF
30 March 2020	Temporary stop of recruitment due to Covid 19
19 May 2020	Resumption of recruitment after temporary stop due to Covid 19

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported