Clinical trial results:
A randomized, controlled, single-blinded, phase II study to investigate the safety and efficacy of intravenous infusions of FERINJECT® versus placebo on platelet activity in patients with iron deficiency and chronic inflammatory bowel disease. The ThromboAct trial

Summary

EudraCT number	2011-004561-33
Trial protocol	AT
Global end of trial date	06 September 2016

Results information

Result version number	v1 (current)
This version publication date	19 March 2021
First version publication date	19 March 2021

Trial information

Trial identification

Sponsor protocol code	ThromboAct

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Spitalgasse 23, Vienna, Austria,
Public contact	Medical University of Vienna, Depar, Medical University of Vienna, Department for, stefanie.dabsch@meduniwien.ac.at
Scientific contact	Medical University of Vienna, Depar, Medical University of Vienna, Department for, stefanie.dabsch@meduniwien.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	Interim
Date of interim/final analysis	16 February 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 September 2016
Global end of trial reached?	Yes
Global end of trial date	06 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To evaluate the efficacy of iron in comparison to placebo in reducing platelet activity as measured by platelet aggregation

Protection of trial subjects:

anonymization of data
Insurance

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2015
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: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	40
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patient were recruited out of routine visits

Pre-assignment

Screening details:

complete blood Count, questionnaire to screen patients

Period 1

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

Blinding implementation details:

Blinding was done via covering Infusion line and infusion

Arms

Are arms mutually exclusive?	Yes
Arm title	Iron

Arm description:

1000mg iron carboxymaltose Infusion at week 0

Arm type	Active comparator
Investigational medicinal product name	iron carboxymaltose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1000mg diluted in 250ml Sodium Chloride 0.9%

Arm title	Placebo

Arm description:

Placebo control

Arm type	Placebo
Investigational medicinal product name	Sodium Chloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

250ml Sodium Chloride 0.9%

Number of subjects in period 1	Iron	Placebo
Started	20	20
Completed	20	20

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	40	40	
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)	40	40	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	25	25	
Male	15	15	

End points

End points reporting groups	
Reporting group title	Iron
Reporting group description: 1000mg iron carboxymaltose Infusion at week 0	
Reporting group title	Placebo
Reporting group description: Placebo control	

Primary: Change in Platelet aggregometry	
End point title	Change in Platelet aggregometry
End point description:	
End point type	Primary
End point timeframe: Week 4 compared to baseline week 9	

End point values	Iron	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: area under the curve				
median (inter-quartile range (Q1-Q3))	-108 (-208 to -61)	12 (-151 to 135)		

Statistical analyses

Statistical analysis title	Mediantest
Comparison groups	Placebo v Iron
Number of subjects included in analysis	40
Analysis specification	Post-hoc
Analysis type	superiority
P-value	< 0.05
Method	meridian

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Within study period	
Adverse event reporting additional description:	
all adverse events: not-relateted, probably related, possibly related	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Placebo group	
Reporting group title	Iron
Reporting group description:	
Group treated with intravenous iron	

Serious adverse events	Placebo	Iron	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Placebo	Iron	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 20 (10.00%)	4 / 20 (20.00%)	
General disorders and administration site conditions			
Fever			
subjects affected / exposed	0 / 20 (0.00%)	3 / 20 (15.00%)	
occurrences (all)	0	3	
Infections and infestations			
common cold			
subjects affected / exposed	2 / 20 (10.00%)	1 / 20 (5.00%)	
occurrences (all)	2	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported