

**Clinical trial results:****Pilot study for evaluation of growth factor erythropoietin beta for improvement of left ventricular function after coronary interventions****Summary**

EudraCT number	2004-002646-35
Trial protocol	DE
Global end of trial date	31 October 2008

Results information

Result version number	v2 (current)
This version publication date	08 March 2022
First version publication date	19 December 2021
Version creation reason	• Changes to summary attachments new version
Summary attachment (see zip file)	Link-to publication_2004-002646-35 (Link-to-publication-PORTAL_study_2004-002646-35.pdf)

Trial information**Trial identification**

Sponsor protocol code	8514077463
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00568542
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	charite-Universitätsmedizin Berlin
Sponsor organisation address	Augustenburger Platz 1, Berlin, Germany, 13353
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Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
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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	31 October 2008
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 October 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To test the effect of a once weekly dose of erythropietin on left ventricular remodelling after coronary intervention.

Protection of trial subjects:

low dose treatment following PCI (percutaneous coronary intervention is safe and feasible. Safety: Blood pressure, heart rate, measures of subjective well-being ,adverse events (AE), serious adverse events (SAE), serious adverse reactions (SAR)

Background therapy:

Ischemic heart failure is a major public health burden in western societies. Although technical advancements have improved recascularization of ischemic heart tissue in recent years, data on functional improvement concerning the left ventricle suggest a need for optimization of pharamcological therapie. The growth hormone erythropoietin beta has been shown to improve heart function in various animal models of ischemic heart disease.

Evidence for comparator: -

Actual start date of recruitment	18 October 2005
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	Germany: 28
Worldwide total number of subjects	28
EEA total number of subjects	28

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)	28
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

We recruited 32 patients. Four patients withdrew consent or presented with exclusion criteria during the screening phase after providing informed consent. Of the remaining 28 patients, 14 were assigned to receive placebo and 14 to receive epoetin-b

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	EPO group

Arm description:

35 I.E. erythropoietin beta given by subcutaneous injection once per week for 6 months. The drug is self-administered.

Arm type	Experimental
Investigational medicinal product name	Erythropoietin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

35 I.E. kg body weight subcutaneous once per week for 6 months

Arm title	Placebo group
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Arm description:

Placebo to erythropoietin beta

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	NeoRecormon 10.000 patron
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

35 I.E. kg body weight placebo to erythropoietin beta

Number of subjects in period 1	EPO group	Placebo group
Started	14	14
Completed	13	11
Not completed	1	3
Consent withdrawn by subject	-	2
Protocol deviation	1	1

Baseline characteristics

Reporting groups

Reporting group title	EPO group
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Reporting group description:

35 I.E. erythropoietin beta given by subcutaneous injection once per week for 6 months. The drug is self-administered.

Reporting group title	Placebo group
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Reporting group description:

Placebo to erythropoietin beta

Reporting group values	EPO group	Placebo group	Total
Number of subjects	14	14	28
Age categorical			
Units: Subjects			
Adults (18-74)	14	14	28
Age continuous			
Units: years			
arithmetic mean	61.0	61.8	
standard deviation	± 1.7	± 3.0	-
Gender categorical			
Units: Subjects			
Female	1	2	3
Male	12	9	21
N/A	1	3	4

End points

End points reporting groups

Reporting group title	EPO group
Reporting group description: 35 I.E. erythropoietin beta given by subcutaneous injection once per week for 6 months. The drug is self-administered.	
Reporting group title	Placebo group
Reporting group description: Placebo to erythropoietin beta	

Primary: change of the erythropoietin levels compared to the baseline levels

End point title	change of the erythropoietin levels compared to the baseline levels ^[1]
End point description: The individual change in ejection fraction between baseline and 6-month follow-up measured by echocardiography and cardiac MRI was greater in the EPO group than in the placebo group. Both methods of LV function measurement performed in the trial, namely cardiac MRI and echocardiography, are reported in a combined fashion due to the low patient numbers	
End point type	Primary
End point timeframe: 6months after baseline	

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: Statistical analyses were not performed due to limited number of subjects.

End point values	EPO group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	11		
Units: mg/dl				
arithmetic mean (standard deviation)				
echocardiographic ejection fraction EF mean (%)	5.7 (± 1.9)	0.3 (± 1.6)		
cardiac MRI ejection fraction EF mean (%)	3.1 (± 1.6)	-1.9 (± 1.2)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

6months

Assessment type	Systematic
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Dictionary used

Dictionary name	own
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Dictionary version	1
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Reporting groups

Reporting group title	EPO-Group
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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: No non-serious events were given

Serious adverse events	EPO-Group	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
decompensated heart failure			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	EPO-Group	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported