



Clinical trial results:

Effect of pravastatin or fluvastatin and add-on valsartan on inflammatory markers and peripheral endothelial function in patients with acute coronary syndrome

Summary

EudraCT number	2004-003235-31
Trial protocol	AT
Global end of trial date	31 January 2006

Results information

Result version number	v1 (current)
This version publication date	12 February 2022
First version publication date	12 February 2022

Trial information

Trial identification

Sponsor protocol code	Prof. Franz Weidinger
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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	Prof. Dr. med. Franz Weidinger, Klinik Landstraße, Juchgasse 25, 1030 Wien, +43 (0) 1 71165 2231, PostKAR2ME@gesundheitsverbund.at
Scientific contact	Prof. Dr. med. Franz Weidinger, Klinik Landstraße, Juchgasse 25, 1030 Wien, +43 (0) 1 71165 2231, PostKAR2ME@gesundheitsverbund.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	31 January 2006
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	31 January 2006
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

- Investigation whether fluvastatin and pravastatin have different effects on hsCRP, sCD40L
- Investigation whether add-on therapy with valsartan causes an additional decrease of hsCRP and sCD40L

Protection of trial subjects:

N/A

Background therapy:

-

Evidence for comparator:

-

Actual start date of recruitment	31 January 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	Austria: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No patients were recruited for this trial. "99999" is a value for 0 participants.

Pre-assignment

Screening details:

N/A

Period 1

Period 1 title	Treatment (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Treatment
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Arm description:

No patients were recruited for this trial. "99999" is a value for 0 participants.

Arm type	Experimental
Investigational medicinal product name	Fluvastatine
Investigational medicinal product code	
Other name	Lescol
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One tablet daily (80 milligram).

Investigational medicinal product name	Valsartan
Investigational medicinal product code	
Other name	Diovan
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Add-on medication, dosage depends on the medical history of the subject.

Investigational medicinal product name	Pravastatine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One tablet daily (40 milligram)

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One tablet daily.

Number of subjects in period 1	Treatment
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Treatment
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Reporting group description: -

Reporting group values	Treatment	Total	
Number of subjects	99999	99999	
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)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender categorical			
Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Treatment
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Reporting group description:

No patients were recruited for this trial. "99999" is a value for 0 participants.

Primary: Fluvastatin/ Pravastatin

End point title	Fluvastatin/ Pravastatin ^[1]
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End point description:

End point type	Primary
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End point timeframe:

N/A

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: No patients were recruited for this trial, therefore no statistical analysis was performed.

End point values	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	99999			
Units: N/A				
number (not applicable)	99999			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

31.01.2005-31.01.2006

Assessment type Systematic

Dictionary used

Dictionary name CTCAE

Dictionary version 3.0

Reporting groups

Reporting group title Treatment

Reporting group description:

No patients were recruited for this trial. "99999" is a value for 0 participants.

Serious adverse events	Treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		

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 patients were recruited for this trial, therefore no AEs and SAEs were observed.

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No patients were enrolled in this trial. "99999" is a value for 0 participants, as it was not possible to fill in "0" for the number of included patients.

Notes: