



## 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 |
|-----------------------|-----------------------|

##### 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:

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**Results analysis stage**

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|                                                      |                 |
|------------------------------------------------------|-----------------|
| Analysis stage                                       | Final           |
| Date of interim/final analysis                       | 31 January 2006 |
| Is this the analysis of the primary completion data? | No              |

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|                                  |                 |
|----------------------------------|-----------------|
| Global end of trial reached?     | Yes             |
| Global end of trial date         | 31 January 2006 |
| Was the trial ended prematurely? | Yes             |

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Notes:

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**General information about the trial**

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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

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Background therapy:

-

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Evidence for comparator:

-

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|                                                           |                 |
|-----------------------------------------------------------|-----------------|
| Actual start date of recruitment                          | 31 January 2005 |
| Long term follow-up planned                               | No              |
| Independent data monitoring committee (IDMC) involvement? | No              |

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Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

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|                                      |                |
|--------------------------------------|----------------|
| Country: Number of subjects enrolled | Austria: 99999 |
| Worldwide total number of subjects   | 99999          |
| EEA total number of subjects         | 99999          |

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Notes:

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**Subjects enrolled per age group**

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|                                           |       |
|-------------------------------------------|-------|
| 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     |

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## 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 |
|-----------|-----------|

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.

| <b>Number of subjects in period 1</b> | Treatment |
|---------------------------------------|-----------|
| Started                               | 99999     |
| Completed                             | 99999     |

## Baseline characteristics

### Reporting groups

| Reporting group title          | Treatment |
|--------------------------------|-----------|
| Reporting group description: - |           |

| Reporting group values                                | Treatment | Total |  |
|-------------------------------------------------------|-----------|-------|--|
| Number of subjects                                    | 99999     | 99999 |  |
| Age categorical                                       |           |       |  |
| Units: Subjects                                       |           |       |  |
| In utero                                              | 0         | 0     |  |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0         | 0     |  |
| Newborns (0-27 days)                                  | 0         | 0     |  |
| Infants and toddlers (28 days-23<br>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 |
| 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 <sup>[1]</sup> |
| End point description: |                                         |

|                      |         |
|----------------------|---------|
| End point type       | Primary |
| 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<sup>[1]</sup>

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

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### 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: