# Clinical trial results:
# A Multicenter, Open-label Extension (OLE) Study to Assess the Long-term Safety and Efficacy of Evolocumab

## Summary

| | |
|---|---|
| EudraCT number | 2014-001524-30 |
| Trial protocol | HU IT BE DE IS GB ES CZ IE NL SE GR |
| Global end of trial date | 09 March 2018 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 16 March 2019 |
| First version publication date | 16 March 2019 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | 20140128 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02304484 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Amgen Inc. |
| Sponsor organisation address | One Amgen Center Drive, Thousand Oaks, CA, United States, 91320 |
| Public contact | IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com |
| Scientific contact | IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com |

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 | 09 March 2018 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 09 March 2018 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this study was to characterize the safety and tolerability of long-term administration of evolocumab in subjects with known coronary artery disease and hypercholesterolemia.

Protection of trial subjects:

This study was conducted in accordance with International Council for Harmonisation (ICH) Good Clinical Practice (GCP) regulations/guidelines.
The protocol, proposed informed consent form, and other written subject information, was submitted to the Independent Ethics Committee/Institutional Review Board (IEC/IRB) for written approval before recruitment of subjects into the study.
Before a subject's participation in the clinical study, the investigator was responsible for obtaining written informed consent from the subject after adequate explanation of the aims, methods, anticipated benefits, and potential hazards of the study and before any protocol-specific screening procedures or any investigational products were administered.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 24 November 2014 |
| 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 | Canada: 50 |
| Country: Number of subjects enrolled | United States: 72 |
| Country: Number of subjects enrolled | Belgium: 22 |
| Country: Number of subjects enrolled | Czech Republic: 30 |
| Country: Number of subjects enrolled | France: 17 |
| Country: Number of subjects enrolled | Germany: 3 |
| Country: Number of subjects enrolled | Greece: 9 |
| Country: Number of subjects enrolled | Hungary: 128 |
| Country: Number of subjects enrolled | Iceland: 7 |
| Country: Number of subjects enrolled | Ireland: 1 |
| Country: Number of subjects enrolled | Israel: 2 |
| Country: Number of subjects enrolled | Italy: 22 |
| Country: Number of subjects enrolled | Netherlands: 120 |
| Country: Number of subjects enrolled | Norway: 14 |
| Country: Number of subjects enrolled | Poland: 80 |
| Country: Number of subjects enrolled | Russian Federation: 63 |

| | |
|---|---|
| Country: Number of subjects enrolled | Spain: 20 |
| Country: Number of subjects enrolled | Sweden: 10 |
| Country: Number of subjects enrolled | Switzerland: 2 |
| Country: Number of subjects enrolled | United Kingdom: 3 |
| Country: Number of subjects enrolled | Argentina: 8 |
| Country: Number of subjects enrolled | Brazil: 1 |
| Country: Number of subjects enrolled | Chile: 8 |
| Country: Number of subjects enrolled | Mexico: 6 |
| Country: Number of subjects enrolled | Australia: 18 |
| Country: Number of subjects enrolled | Korea, Republic of: 7 |
| Country: Number of subjects enrolled | Malaysia: 7 |
| Country: Number of subjects enrolled | South Africa: 38 |
| Country: Number of subjects enrolled | Taiwan: 2 |
| Worldwide total number of subjects | 770 |
| EEA total number of subjects | 486 |

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) | 536 |
| From 65 to 84 years | 234 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

This study was conducted at 126 centers in 29 countries in the regions of Europe (71.8%), North America (15.8%), Asia Pacific (9.4%) and Latin America (3.0%). Participants were enrolled from 24 November 2014 to 31 August 2016.

### Pre-assignment

Screening details:

Participants who successfully completed week 80 of the parent Study 20120153 (2012-004208-37) and did not discontinue study drug in the parent study for any reason were eligible for this study. All participants received open-label evolocumab.

### Period 1

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

### Arms

| | |
|---|---|
| **Arm title** | Evolocumab |

Arm description:

Participants received 420 mg evolocumab once a month for up to 2 years.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Evolocumab |
| Investigational medicinal product code | AMG 145 |
| Other name | Repatha |
| Pharmaceutical forms | Solution for injection in pre-filled pen |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Evolocumab 420 mg administered by subcutaneous injection once a month

| **Number of subjects in period 1** | Evolocumab |
|---|---|
| Started | 770 |
| Completed | 745 |
| Not completed | 25 |
| Adverse event, serious fatal | 9 |
| Consent withdrawn by subject | 14 |
| Lost to follow-up | 2 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Evolocumab |
| Reporting group description: | |
| Participants received 420 mg evolocumab once a month for up to 2 years. | |

| Reporting group values | Evolocumab | Total | |
|---|---|---|---|
| Number of subjects | 770 | 770 | |
| Age, Customized<br>Units: Subjects | | | |
| 18 - 64 years | 536 | 536 | |
| ≥ 65 years | 234 | 234 | |
| Age Continuous<br>Units: years | | | |
| arithmetic mean | 59.5 | | |
| standard deviation | ± 8.8 | - | |
| Sex: Female, Male<br>Units: Subjects | | | |
| Female | 202 | 202 | |
| Male | 568 | 568 | |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| American Indian or Alaska Native | 1 | 1 | |
| Asian | 19 | 19 | |
| Black or African American | 5 | 5 | |
| Native Hawaiian or Other Pacific Islander | 1 | 1 | |
| White | 729 | 729 | |
| Multiple | 11 | 11 | |
| Other | 4 | 4 | |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 38 | 38 | |
| Not Hispanic or Latino | 732 | 732 | |
| Unknown or Not Reported | 0 | 0 | |
| Low-density Lipoprotein Cholesterol (LDL-C) Concentration | | | |
| Baseline is defined as parent study 20120153 baseline. | | | |
| Units: mg/dL | | | |
| arithmetic mean | 92.2 | | |
| standard deviation | ± 27.3 | - | |

## End points

### End points reporting groups

| Reporting group title | Evolocumab |
|---|---|

Reporting group description:

Participants received 420 mg evolocumab once a month for up to 2 years.

### Primary: Number of Participants with Adverse Events

| End point title | Number of Participants with Adverse Events[1] |
|---|---|

End point description:

The severity of each adverse event (AE) was graded using the Common Terminology Criteria for Adverse Events (CTCAE) version 4.03 criteria, where Grade 1 = Mild AE, Grade 2 = Moderate AE, Grade 3 = Severe or medically significant AE, Grade 4 = Life-threatening consequences, and Grade 5 = death related to AE. An adverse device effect was defined as any adverse event related to the use of a medical device (autoinjector/pen or automated mini doser [AMD]), including but not limited to, AEs resulting from insufficient or inadequate Instructions for Use, AEs resulting from any malfunction of the device, or AEs resulting from use error or from intentional misuse of the device.

| End point type | Primary |
|---|---|

End point timeframe:

From first dose of evolocumab up to 30 days after the last dose, or end of study, whichever was earlier, up to 108 weeks

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 in this open-label extension study were descriptive in nature. No statistical inference was planned.

| End point values | Evolocumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 770 | | | |
| Units: participants | | | | |
| Any adverse event | 526 | | | |
| Adverse events ≥ Grade 2 | 415 | | | |
| Adverse events ≥ Grade 3 | 206 | | | |
| Adverse events ≥ Grade 4 | 38 | | | |
| Serious adverse events | 153 | | | |
| AEs leading to discontinuation of evolocumab | 14 | | | |
| Fatal adverse events | 6 | | | |
| Device-related adverse events | 12 | | | |
| Device-related adverse events ≥ Grade 2 | 2 | | | |
| Device-related adverse events ≥ Grade 3 | 1 | | | |
| Device-related adverse events ≥ Grade 4 | 0 | | | |
| Serious device-related adverse events | 0 | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percent Change from Baseline in Low-density Lipoprotein Cholesterol (LDL-C)

| End point title | Percent Change from Baseline in Low-density Lipoprotein Cholesterol (LDL-C) |
|---|---|

End point description:

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline (of study 20120153) and weeks 0, 4, 12, 24, 36, 48, 52, 76, and 104 of study 20140128

| **End point values** | Evolocumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 770 | | | |
| Units: percent change | | | | |
| arithmetic mean (standard deviation) | | | | |
| Percent change from baseline to week 0 (n = 751) | -21.52 (± 40.49) | | | |
| Percent change from baseline to week 4 (n = 752) | -57.23 (± 22.19) | | | |
| Percent change from baseline to week 12 (n = 746) | -58.54 (± 25.60) | | | |
| Percent change from baseline to week 24 (n = 747) | -55.26 (± 28.51) | | | |
| Percent change from baseline to week 36 (n = 738) | -51.72 (± 30.34) | | | |
| Percent change from baseline to week 48 (n = 709) | -53.65 (± 28.72) | | | |
| Percent change from baseline to week 52 (n = 725) | -51.30 (± 28.48) | | | |
| Percent change from baseline to week 76 (n = 722) | -51.73 (± 32.49) | | | |
| Percent change from baseline to week 104 (n = 607) | -47.94 (± 36.49) | | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Total deaths are reported from the 1st dose of evolocumab up to the end of study; AEs are reported from the 1st dose of evolocumab up to 30 days after the last dose or end of study, whichever is earlier. The maximum duration of treatment was 24.6 months.

| | |
|---|---|
| Assessment type | Systematic |

### Dictionary used

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|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 20.1 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Evolocumab |

Reporting group description:

Participants received 420 mg evolocumab once a month for up to 2 years.

| Serious adverse events | Evolocumab | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 153 / 770 (19.87%) | | |
| number of deaths (all causes) | 9 | | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Benign salivary gland neoplasm | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bladder transitional cell carcinoma metastatic | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Colon adenoma | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastric cancer | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Lung cancer metastatic | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lung neoplasm malignant | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Metastases to stomach | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Metastatic gastric cancer | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Metastases to urinary tract | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Oesophageal carcinoma | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Prostate cancer | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Metastatic malignant melanoma | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| Hypotension | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Venous thrombosis | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Chest discomfort | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Chest pain | | | |
| subjects affected / exposed | 4 / 770 (0.52%) | | |
| occurrences causally related to treatment / all | 0 / 4 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Fatigue | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Malaise | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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|---|---|---|---|---|
| Non-cardiac chest pain | | | | |
| subjects affected / exposed | 6 / 770 (0.78%) | | | |
| occurrences causally related to treatment / all | 0 / 6 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sudden death | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Vascular stent occlusion | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Immune system disorders | | | | |
| Contrast media reaction | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Reproductive system and breast disorders | | | | |
| Benign prostatic hyperplasia | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory, thoracic and mediastinal disorders | | | | |
| Acute respiratory failure | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Chronic obstructive pulmonary disease | | | | |
| subjects affected / exposed | 4 / 770 (0.52%) | | | |
| occurrences causally related to treatment / all | 0 / 5 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Dyspnoea | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypoxia | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Idiopathic pulmonary fibrosis | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonitis | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| **Psychiatric disorders** | | | |
| Suicidal ideation | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| **Product issues** | | | |
| Device loosening | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| **Investigations** | | | |
| Anticoagulation drug level above therapeutic | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|---|---|---|
| Injury, poisoning and procedural complications | | | |
| Anastomotic leak | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ankle fracture | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Contusion | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Concussion | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Femoral neck fracture | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Fall | | | |
| subjects affected / exposed | 3 / 770 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Epicondylitis | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hip fracture | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | | |
|---|---|---|---|---|
| Intentional overdose | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Meniscus injury | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Muscle strain | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pelvic fracture | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Post procedural haemorrhage | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Radius fracture | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Spinal compression fracture | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Subarachnoid haematoma | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Thoracic vertebral fracture | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Toxicity to various agents | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac disorders | | | | |
| Acute coronary syndrome | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Acute myocardial infarction | | | | |
| subjects affected / exposed | 4 / 770 (0.52%) | | | |
| occurrences causally related to treatment / all | 0 / 5 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Angina pectoris | | | | |
| subjects affected / exposed | 13 / 770 (1.69%) | | | |
| occurrences causally related to treatment / all | 0 / 14 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Angina unstable | | | | |
| subjects affected / exposed | 5 / 770 (0.65%) | | | |
| occurrences causally related to treatment / all | 0 / 6 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Arteriospasm coronary | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Atrial fibrillation | | | | |
| subjects affected / exposed | 5 / 770 (0.65%) | | | |
| occurrences causally related to treatment / all | 0 / 6 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Atrial flutter | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Atrioventricular block complete | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac arrest | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Cardiac failure | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac failure acute | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac failure chronic | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac failure congestive | | | | |
| subjects affected / exposed | 3 / 770 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac ventricular thrombosis | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congestive cardiomyopathy | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Coronary artery disease | | | | |
| subjects affected / exposed | 4 / 770 (0.52%) | | | |
| occurrences causally related to treatment / all | 0 / 4 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Coronary artery stenosis | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Myocardial infarction | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Left ventricular failure | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Palpitations | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Myocardial ischaemia | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pericarditis | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sinus bradycardia | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sinus tachycardia | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Supraventricular tachycardia | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ventricular tachycardia | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Nervous system disorders | | | | |
| Carotid artery stenosis | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Carpal tunnel syndrome | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cervical radiculopathy | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Dizziness | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Generalised tonic-clonic seizure | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ischaemic stroke | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Parkinsonism | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sciatica | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Syncope | | | | |
| subjects affected / exposed | 3 / 770 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Transient ischaemic attack | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 1 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Blood and lymphatic system disorders | | | | |
| Haemorrhagic anaemia | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ear and labyrinth disorders | | | | |
| Tinnitus | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Vertigo | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 770 (0.26%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Eye disorders | | | |
| Cataract | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Diplopia | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Abdominal adhesions | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Colitis | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Duodenal perforation | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dyspepsia | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastritis erosive | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Incarcerated umbilical hernia | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Inguinal hernia | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Intestinal haemorrhage | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Large intestine polyp | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pancreatitis | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pancreatitis acute | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pancreatitis chronic | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Umbilical hernia | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Peptic ulcer | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Upper gastrointestinal haemorrhage | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Vomiting | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatobiliary disorders | | | | |
| Bile duct stone | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cholangitis | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cholecystitis acute | | | | |
| subjects affected / exposed | 3 / 770 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cholecystitis chronic | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cholelithiasis | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Portal vein thrombosis | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Skin and subcutaneous tissue disorders | | | | |
| Skin haemorrhage | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Diabetic foot | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Angioedema | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Skin ulcer | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Renal and urinary disorders | | | | |
| Acute kidney injury | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haematuria | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Renal cyst | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Musculoskeletal and connective tissue disorders | | | | |
| Arthralgia | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Arthritis | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lumbar spinal stenosis | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 4 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Musculoskeletal chest pain | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Osteoarthritis | | | | |
| subjects affected / exposed | 5 / 770 (0.65%) | | | |
| occurrences causally related to treatment / all | 0 / 5 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pain in extremity | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Periarthritis | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Synovial cyst | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infections and infestations | | | | |
| Appendicitis | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cellulitis | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bacterial colitis | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Chronic sinusitis | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Dengue fever | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Diabetic foot infection | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Diverticulitis | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lung abscess | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lymph gland infection | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pertussis | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia | | | | |
| subjects affected / exposed | 4 / 770 (0.52%) | | | |
| occurrences causally related to treatment / all | 0 / 5 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia bacterial | | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sepsis | | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Staphylococcal osteomyelitis | | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 2 / 770 (0.26%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gout | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Type 1 diabetes mellitus | | | |
| subjects affected / exposed | 1 / 770 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| **Non-serious adverse events** | Evolocumab | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 49 / 770 (6.36%) | | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 49 / 770 (6.36%) | | |
| occurrences (all) | 54 | | |

## 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