Clinical trial results:
A Randomized, Multicenter, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Oral Sumatriptan for the Acute Treatment of Migraine in Children and Adolescents

Summary

EudraCT number	2015-004880-35
Trial protocol	Outside EU/EEA
Global end of trial date	03 December 2010

Results information

Result version number	v1 (current)
This version publication date	26 January 2017
First version publication date	26 January 2017

Trial information

Trial identification

Sponsor protocol code	111035

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,

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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 February 2011
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 December 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

TBD

Protection of trial subjects:

Not Applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 September 2009
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	Japan: 178
Worldwide total number of subjects	178
EEA total number of subjects	0

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)	29
Adolescents (12-17 years)	149
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 178 participants (par.) were enrolled into the study (89 par. - Placebo arm, 44 par. - Sumatriptan 25 mg, 35 par. - Sumatriptan 50 mg). Subject disposition is presented for the Full Analysis Set, comprised of all participants who took at least one dose of investigational product and provided any post-treatment efficacy assessment.

Period 1

Period 1 title	Overall Study (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	Placebo

Arm description:

Participants took 2 tablets of placebo matched to sumatriptan 25 milligrams (mg) within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on a 5-grade, self-rating scale to assess the pain intensity of a migraine: 1 = none, 2 = mild, 3 = mild to moderate, 4 = moderate to severe, and 5 = severe.

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

Dosage and administration details:

Two tablets matching the Sumatriptan 25 mg administered orally (within 30 minutes) after development of migraine associated with score 3 or more severe pain on a 5-grade scale.

Arm title	Sumatriptan 25 mg

Arm description:

Participants took 1 tablet of sumatriptan 25 mg and 1 tablet of placebo matched to sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.

Arm type	Active comparator
Investigational medicinal product name	Sumatriptan 25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One tablet administered orally (within 30 minutes) after development of migraine associated with score 3 or more severe pain on a 5-grade scale.

Arm title	Sumatriptan 50 mg

Arm description:

Participants took 2 tablets of sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.

Arm type	Active comparator
Investigational medicinal product name	Sumatriptan 50 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Two tablets of Sumatriptan 25 mg administered orally (within 30 minutes) after development of migraine associated with score 3 or more severe pain on a 5-grade scale.

Number of subjects in period 1[1]	Placebo	Sumatriptan 25 mg	Sumatriptan 50 mg
Started	70	33	41
Completed	70	33	41

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: A total of 178 participants (par.) were enrolled into the study (89 par. - Placebo arm, 44 par. - Sumatriptan 25 mg, 35 par. - Sumatriptan 50 mg). Subject disposition is presented for the Full Analysis Set,

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants took 2 tablets of placebo matched to sumatriptan 25 milligrams (mg) within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on a 5-grade, self-rating scale to assess the pain intensity of a migraine: 1 = none, 2 = mild, 3 = mild to moderate, 4 = moderate to severe, and 5 = severe.	
Reporting group title	Sumatriptan 25 mg
Reporting group description:	
Participants took 1 tablet of sumatriptan 25 mg and 1 tablet of placebo matched to sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.	
Reporting group title	Sumatriptan 50 mg
Reporting group description:	
Participants took 2 tablets of sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.	

Reporting group values	Placebo	Sumatriptan 25 mg	Sumatriptan 50 mg
Number of subjects	70	33	41
Age categorical Units: Subjects			
Age continuous			
Baseline characteristics were collected in the Full Analysis Set (FAS), comprised of all participants who took at least one dose of investigational product (IP) and provided any post-treatment efficacy assessment. Participants who withdrew from the study before completion did not receive IP and thus contributed no baseline data.			
Units: years			
arithmetic mean	13.9	14.5	14.1
standard deviation	± 2.04	± 2.18	± 1.96
Gender categorical			
Baseline characteristics were collected in the Full Analysis Set (FAS), comprised of all participants who took at least one dose of investigational product (IP) and provided any post-treatment efficacy assessment. Participants who withdrew from the study before completion did not receive IP and thus contributed no baseline data.			
Units: Subjects			
Female	39	17	28
Male	31	16	13
Race/Ethnicity, Customized			
Baseline characteristics were collected in the Full Analysis Set (FAS), comprised of all participants who took at least one dose of investigational product (IP) and provided any post-treatment efficacy assessment. Participants who withdrew from the study before completion did not receive IP and thus contributed no baseline data.			
Units: Subjects			
Asian - Japanese Heritage	70	33	41

Reporting group values	Total		
Number of subjects	144		

Age categorical Units: Subjects			

Age continuous			
Baseline characteristics were collected in the Full Analysis Set (FAS), comprised of all participants who took at least one dose of investigational product (IP) and provided any post-treatment efficacy assessment. Participants who withdrew from the study before completion did not receive IP and thus contributed no baseline data.			
Units: years arithmetic mean standard deviation	 -		
Gender categorical			
Baseline characteristics were collected in the Full Analysis Set (FAS), comprised of all participants who took at least one dose of investigational product (IP) and provided any post-treatment efficacy assessment. Participants who withdrew from the study before completion did not receive IP and thus contributed no baseline data.			
Units: Subjects			
Female Male	84 60		
Race/Ethnicity, Customized			
Baseline characteristics were collected in the Full Analysis Set (FAS), comprised of all participants who took at least one dose of investigational product (IP) and provided any post-treatment efficacy assessment. Participants who withdrew from the study before completion did not receive IP and thus contributed no baseline data.			
Units: Subjects			
Asian - Japanese Heritage	144		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants took 2 tablets of placebo matched to sumatriptan 25 milligrams (mg) within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on a 5-grade, self-rating scale to assess the pain intensity of a migraine: 1 = none, 2 = mild, 3 = mild to moderate, 4 = moderate to severe, and 5 = severe.	
Reporting group title	Sumatriptan 25 mg
Reporting group description:	
Participants took 1 tablet of sumatriptan 25 mg and 1 tablet of placebo matched to sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.	
Reporting group title	Sumatriptan 50 mg
Reporting group description:	
Participants took 2 tablets of sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.	
Subject analysis set title	Sumatriptan Pooled
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
All participants receiving either sumatriptan 25 mg or 50 mg	

Primary: Percentage of Participants Who Reported Pain Relief at 120 Minutes Post-Treatment

End point title	Percentage of Participants Who Reported Pain Relief at 120 Minutes Post-Treatment[1]
End point description:	
Pain relief was defined as at least a 2-grade reduction in pain intensity on a 5-grade scale in participants who had not used headache rescue medication before assessment. A pain intensity score of 5 was assigned for all subsequent assessments if a participant took rescue medication (a single oral dose for the treatment of migraine pain or associated symptoms). The 5-grade scale is a participant's self-rating scale to assess the pain intensity of a migraine with the following scores: 1 = none, 2 = mild, 3 = mild to moderate, 4 = moderate to severe, and 5 = severe.	
End point type	Primary
End point timeframe:	
120 minutes post-treatment (Randomization through Final Visit [Week 6])	

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period.

End point values	Placebo	Sumatriptan Pooled		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	70[2]	74[3]		
Units: percentage of participants				
number (not applicable)	38.6	31.1		

Notes:

[2] - Full Analysis Set (FAS): all participants in the Safety Population

[3] - Full Analysis Set (FAS): all participants in the Safety Population

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

PERCENTAGE OF PARTICIPANTS WHO REPORTED PAIN RELIEF AT 120 MINUTES POST-TREATMENT

Comparison groups	Placebo v Sumatriptan Pooled
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.345 [4]
Method	Chi-squared
Parameter estimate	Percent Difference
Point estimate	-7.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.02
upper limit	8.04

Notes:

[4] - Multiplicity was not considered because the primary analysis included a single statistical comparison.

Secondary: Percentage of Participants Who Reported Pain Relief at 30, 60, 120, and 240 Minutes Post-Treatment

End point title	Percentage of Participants Who Reported Pain Relief at 30, 60, 120, and 240 Minutes Post-Treatment

End point description:

Pain relief was defined as at least a 2-grade reduction in pain intensity on a 5-grade scale in participants who had not used headache rescue medication before assessment. A pain intensity score of 5 was assigned for all subsequent assessments if a participant took rescue medication (a single oral dose for the treatment of migraine pain or associated symptoms). The 5-grade scale is a participant's self-rating scale to assess the pain intensity of a migraine with the following scores: 1 = none, 2 = mild, 3 = mild to moderate, 4 = moderate to severe, and 5 = severe.

End point type	Secondary

End point timeframe:

30, 60, 120, and 240 minutes post-treatment (Randomization through Final Visit [Week 6])

End point values	Placebo	Sumatriptan 25 mg	Sumatriptan 50 mg	Sumatriptan Pooled
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	70[5]	33[6]	41[7]	74[8]
Units: percentage of participants				
number (not applicable)				
30 minutes post-treatment	4.3	0	9.8	5.4
60 minutes post-treatment	18.6	9.1	7.3	8.1
120 minutes post-treatment	38.6	33.3	29.3	31.1
240 minutes post-treatment	51.4	66.7	61	63.5

Notes:

[5] - FAS. The analysis was performed on the LOCF dataset.

[6] - FAS. The analysis was performed on the LOCF dataset.

[7] - FAS. The analysis was performed on the LOCF dataset.

[8] - FAS. The analysis was performed on the LOCF dataset.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Were Pain Free at 30, 60, 120, and 240 Minutes Post-Treatment

End point title	Percentage of Participants Who Were Pain Free at 30, 60, 120, and 240 Minutes Post-Treatment

End point description:

Pain free was defined as a post-treatment pain intensity score of 1 on a 5-grade scale in participants who had not used headache rescue medication before assessment. A pain intensity score of 5 was assigned for all subsequent assessments if a participant took a rescue medication. The 5-grade scale is a participant's self-rating scale to assess the pain intensity of a migraine with the following scores: 1 = none, 2 =mild, 3=mild to moderate, 4=moderate to severe, and 5=severe.

End point type	Secondary

End point timeframe:

30, 60, 120, and 240 minutes post-treatment (Randomization through Final Visit [Week 6])

End point values	Placebo	Sumatriptan 25 mg	Sumatriptan 50 mg	Sumatriptan Pooled
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	70[9]	33[10]	41[11]	74[12]
Units: percentage of participants				
number (not applicable)				
30 minutes post-treatment	2.9	0	2.4	1.4
60 minutes post-treatment	12.9	3	2.4	2.7
120 minutes post-treatment	28.6	24.2	19.5	21.6
240 minutes post-treatment	47.1	63.6	39	50

Notes:

[9] - FAS. The analysis was performed on the LOCF dataset.

[10] - FAS. The analysis was performed on the LOCF dataset.

[11] - FAS. The analysis was performed on the LOCF dataset.

[12] - FAS. The analysis was performed on the LOCF dataset.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Were Photophobia Free at 30, 60, 120, and 240 Minutes Post-Treatment

End point title	Percentage of Participants Who Were Photophobia Free at 30, 60, 120, and 240 Minutes Post-Treatment

End point description:

Photophobia (sensitivity to light) is one of the associated symptoms of a migraine. A participant was assessed as photophobia free when the symptom was recorded as "absent" at each time point in his or her patient diary. Photophobia was recorded as "present" for all subsequent assessments if a participant took rescue medication.

End point type	Secondary

End point timeframe:

30, 60, 120, and 240 minutes post-treatment (Randomization through Final Visit [Week 6])

End point values	Placebo	Sumatriptan 25 mg	Sumatriptan 50 mg	Sumatriptan Pooled
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	36[13]	15[14]	13[15]	28[16]
Units: percentage of participants				
number (not applicable)				
30 minutes post-treatment	16.7	13.3	15.4	14.3
60 minutes post-treatment	44.4	26.7	38.5	32.1
120 minutes post-treatment	52.8	60	46.2	53.6
240 minutes post-treatment	69.4	80	69.2	75

Notes:

[13] - FAS. The analysis was performed on the LOCF dataset.

[14] - FAS. The analysis was performed on the LOCF dataset.

[15] - FAS. The analysis was performed on the LOCF dataset.

[16] - FAS. The analysis was performed on the LOCF dataset.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Were Phonophobia Free at 30, 60, 120, and 240 Minutes Post-Treatment

End point title	Percentage of Participants Who Were Phonophobia Free at 30, 60, 120, and 240 Minutes Post-Treatment

End point description:

Phonophobia (sensitivity to sound) is one of the associated symptoms of a migraine. A participant was assessed as phonophobia free when the symptom was recorded as "absent" at each time point in his or her patient diary. Phonophobia was recorded as "present" for all subsequent assessments if a participant took rescue medication.

End point type	Secondary

End point timeframe:

30, 60, 120, and 240 minutes post-treatment (Randomization through Final Visit [Week 6])

End point values	Placebo	Sumatriptan 25 mg	Sumatriptan 50 mg	Sumatriptan Pooled
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	22[17]	14[18]	16[19]	30[20]
Units: percentage of participants				
number (not applicable)				
30 minutes post-treatment	22.7	50	12.5	30
60 minutes post-treatment	45.5	57.1	25	40
120 minutes post-treatment	63.6	64.3	43.8	53.3
240 minutes post-treatment	72.7	78.6	68.8	73.3

Notes:

[17] - FAS. The analysis was performed on LOCF dataset.

[18] - FAS. The analysis was performed on LOCF dataset.

[19] - FAS. The analysis was performed on LOCF dataset.

[20] - FAS. The analysis was performed on LOCF dataset.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Were Nausea Free at 30, 60, 120, and 240 Minutes Post-Treatment

End point title	Percentage of Participants Who Were Nausea Free at 30, 60, 120, and 240 Minutes Post-Treatment

End point description:

Nausea is one of the associated symptoms of a migraine. A participant was assessed as nausea free when the symptom was recorded as "absent" at each time point in his or her patient diary. Nausea was recorded as "present" for all subsequent assessments if a participant took rescue medication.

End point type	Secondary

End point timeframe:

30, 60, 120, and 240 minutes post-treatment (Randomization through Final Visit [Week 6])

End point values	Placebo	Sumatriptan 25 mg	Sumatriptan 50 mg	Sumatriptan Pooled
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	21[21]	10[22]	8[23]	18[24]
Units: percentage of participants				
number (not applicable)				
30 minutes post-treatment	47.6	40	12.5	27.8
60 minutes post-treatment	66.7	40	12.5	27.8
120 minutes post-treatment	81	70	50	61.1
240 minutes post-treatment	81	70	50	61.1

Notes:

[21] - FAS. The analysis was performed on the LOCF dataset.

[22] - FAS. The analysis was performed on the LOCF dataset.

[23] - FAS. The analysis was performed on the LOCF dataset.

[24] - FAS. The analysis was performed on the LOCF dataset.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Were Free of Vomiting at 30, 60, 120, and 240 Minutes Post-Treatment

End point title	Percentage of Participants Who Were Free of Vomiting at 30, 60, 120, and 240 Minutes Post-Treatment

End point description:

Vomiting is one of the associated symptoms of a migraine. A participant was assessed as being free of vomiting when the symptom was recorded as "absent" at each time point in his or her patient diary. Vomiting was recorded as "present" for all subsequent assessments if a participant took a rescue medication.

End point type	Secondary

End point timeframe:

30, 60, 120, and 240 minutes post-treatment (Randomization through Final Visit [Week 6])

End point values	Placebo	Sumatriptan 25 mg	Sumatriptan 50 mg	Sumatriptan Pooled
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[25]	1[26]	0[27]	1[28]
Units: percentage of participants				
number (not applicable)				
30 minutes post-treatment		0		0
60 minutes post-treatment		0		0
120 minutes post-treatment		100		100
240 minutes post-treatment		100		100

Notes:

[25] - FAS. The analysis was performed on the LOCF dataset.

[26] - FAS. The analysis was performed on the LOCF dataset.

[27] - FAS. The analysis was performed on the LOCF dataset.

[28] - FAS. The analysis was performed on the LOCF dataset.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Used Rescue Medication Between the Time of Dosing and 240 Minutes Post-Treatment

End point title	Percentage of Participants Who Used Rescue Medication Between the Time of Dosing and 240 Minutes Post-Treatment

End point description:

Rescue medication included one of the following: a single oral dose of a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, not to exceed the maximum recommended single dose; and anti-emetics (a drug to prevent vomiting).

End point type	Secondary

End point timeframe:

within 240 minutes post-treatment (Randomization through Final Visit [Week 6])

End point values	Placebo	Sumatriptan 25 mg	Sumatriptan 50 mg	Sumatriptan Pooled
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	70[29]	33[30]	41[31]	74[32]
Units: percentage of participants				
number (not applicable)	12.9	12.1	14.6	13.5

Notes:

[29] - FAS. Analysis performed on observed case dataset, a dataset without any imputation of missing data

[30] - FAS. Analysis performed on observed case dataset, a dataset without any imputation of missing data

[31] - FAS. Analysis performed on observed case dataset, a dataset without any imputation of missing

data

[32] - FAS. Analysis performed on observed case dataset, a dataset without any imputation of missing data

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (AEs) and non-serious AEs were collected from the start of IP through follow-up contact (6 weeks plus or minus 7 days).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	13.1

Reporting groups

Reporting group title	Placebo

Reporting group description:

Participants took 2 tablets of placebo matched to sumatriptan 25 milligrams (mg) within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on a 5-grade, self-rating scale to assess the pain intensity of a migraine: 1 = none, 2 = mild, 3 = mild to moderate, 4 = moderate to severe, and 5 = severe.

Reporting group title	Sumatriptan 25 mg

Reporting group description:

Participants took 1 tablet of sumatriptan 25 mg and 1 tablet of placebo matched to sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.

Reporting group title	Sumatriptan 50 mg

Reporting group description:

Participants took 2 tablets of sumatriptan 25 mg within 30 minutes after the development of a migraine associated with a score of 3 or more for pain on the 5-grade scale.

Reporting group title	Sumatriptan Pooled

Reporting group description:

All participants receiving either sumatriptan 25 mg or 50 mg

Serious adverse events	Placebo	Sumatriptan 25 mg	Sumatriptan 50 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 70 (0.00%)	0 / 33 (0.00%)	0 / 41 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Sumatriptan Pooled		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 74 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Placebo	Sumatriptan 25 mg	Sumatriptan 50 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 70 (7.14%)	2 / 33 (6.06%)	3 / 41 (7.32%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	4 / 70 (5.71%)	0 / 33 (0.00%)	0 / 41 (0.00%)
occurrences (all)	4	0	0
Nervous system disorders			
Somnolence			
subjects affected / exposed	1 / 70 (1.43%)	2 / 33 (6.06%)	0 / 41 (0.00%)
occurrences (all)	1	2	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 70 (0.00%)	0 / 33 (0.00%)	3 / 41 (7.32%)
occurrences (all)	0	0	3

Non-serious adverse events	Sumatriptan Pooled		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 74 (6.76%)		
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 74 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Somnolence			
subjects affected / exposed	2 / 74 (2.70%)		
occurrences (all)	2		
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	3 / 74 (4.05%)		
occurrences (all)	3		

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