



Clinical trial results:

Comparative Onset of Action of a Fast Release Aspirin Tablet in a Dental Impaction Pain Model

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2014-005270-11 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 08 September 2011 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 |
| This version publication date | 12 July 2016 |
| First version publication date | 16 July 2015 |

Trial information

Trial identification

| | |
|-----------------------|------------------|
| Sponsor protocol code | BAY1019036/15529 |
|-----------------------|------------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01420094 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Bayer HealthCare AG |
| Sponsor organisation address | Kaiser-Wilhelm-Allee, D-51368, Leverkusen, Germany, |
| Public contact | Clinical Trials Contact, Bayer HealthCare AG, clinical-trials-contact@bayerhealthcare.com |
| Scientific contact | Clinical Trials Contact, Bayer HealthCare AG, clinical-trials-contact@bayerhealthcare.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? | Yes |

Notes:

Results analysis stage

| | |
|--|-------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 08 September 2011 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|-------------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 08 September 2011 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The main objective was to compare the safety and efficacy (onset, duration of relief, and overall efficacy) of a single dose of a fast release formulation of aspirin 1000 milligram (mg) with the safety and efficacy of acetaminophen 1000 mg and placebo for relief of pain following extraction of impacted third molars.

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. This study was conducted according to the principles of the International Conference on Harmonisation harmonised tripartite guideline E6: Good Clinical Practice, the World Medical Association Declaration of Helsinki. Before entering the study, the informed consent form was read by and explained to all subjects and/or their legally authorized representative. Participating subjects signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 16 June 2011 |
| 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 | United States: 510 |
| Worldwide total number of subjects | 510 |
| 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) | 0 |
| Adolescents (12-17 years) | 204 |

| | |
|----------------------|-----|
| Adults (18-64 years) | 306 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The trial was conducted at a single center in the United States between 16 June 2011 (first subject first visit) and 08 September 2011 (last subject last visit).

Pre-assignment

Screening details:

A total of 510 subjects entered the study and were randomly assigned to 1 of 3 treatment groups, and all subjects completed the study.

Period 1

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

Arms

| | |
|------------------------------|--|
| Are arms mutually exclusive? | Yes |
| Arm title | Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

Arm description:

Single oral dose of fast release aspirin tablet 1000 mg (2 x 500 mg) and 2 placebo-matching acetaminophen caplets with a full glass of water (240 milliliter [mL]) between 1-4 hours post dental surgery.

| | |
|--|--------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Placebo-matching acetaminophen |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Single oral dose of fast release aspirin tablet 1000 mg (2 x 500 mg) and 2 placebo-matching acetaminophen caplets with a full glass of water (240 mL) between 1-4 hours post dental surgery.

| | |
|--|--|
| Investigational medicinal product name | Acetylsalicyclic acid (Fast release Aspirin) |
| Investigational medicinal product code | BAY1019036 |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Single oral dose of fast release aspirin tablet 1000 mg (2 x 500 mg) and 2 placebo-matching acetaminophen caplets with a full glass of water (240 mL) between 1-4 hours post dental surgery.

| | |
|------------------|--|
| Arm title | Acetaminophen (Tylenol extra strength) |
|------------------|--|

Arm description:

Single oral dose of acetaminophen (Tylenol extra strength) caplet 1000 mg (2 x 500 mg) and 2 placebo-matching aspirin tablets with a full glass of water (240 mL) between 1-4 hours post dental surgery.

| | |
|--|--|
| Arm type | Active comparator |
| Investigational medicinal product name | Acetaminophen (Tylenol extra strength) |
| Investigational medicinal product code | |
| Other name | Paracetamol |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Single oral dose of acetaminophen (Tylenol extra strength) caplet 1000 mg (2 x 500 mg) and 2 placebo-matching aspirin tablets with a full glass of water (240 mL) between 1-4 hours post dental surgery.

| | |
|--|--------------------------|
| Investigational medicinal product name | Placebo-matching aspirin |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Single oral dose of acetaminophen (Tylenol extra strength) caplet 1000 mg (2 x 500 mg) and 2 placebo-matching aspirin tablets with a full glass of water (240 mL) between 1-4 hours post dental surgery.

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description:

Single oral dose of placebo (2 placebo aspirin tablets and 2 placebo acetaminophen caplets) with a full glass of water (240 mL) between 1-4 hours post dental surgery.

| | |
|--|----------|
| 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:

Single oral dose of placebo (2 placebo aspirin tablets and 2 placebo acetaminophen caplets) with a full glass of water (240 mL) between 1-4 hours post dental surgery.

| Number of subjects in period 1 | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) | Acetaminophen (Tylenol extra strength) | Placebo |
|--------------------------------|--|--|---------|
| | | | |
| Started | 204 | 204 | 102 |
| Completed | 204 | 204 | 102 |

Baseline characteristics

Reporting groups

| | |
|---|---|
| Reporting group title | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Reporting group description: Single oral dose of fast release aspirin tablet 1000 mg (2 x 500 mg) and 2 placebo-matching acetaminophen caplets with a full glass of water (240 milliliter [mL]) between 1-4 hours post dental surgery. | |
| Reporting group title | Acetaminophen (Tylenol extra strength) |
| Reporting group description: Single oral dose of acetaminophen (Tylenol extra strength) caplet 1000 mg (2 x 500 mg) and 2 placebo-matching aspirin tablets with a full glass of water (240 mL) between 1-4 hours post dental surgery. | |
| Reporting group title | Placebo |
| Reporting group description: Single oral dose of placebo (2 placebo aspirin tablets and 2 placebo acetaminophen caplets) with a full glass of water (240 mL) between 1-4 hours post dental surgery. | |

| Reporting group values | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) | Acetaminophen (Tylenol extra strength) | Placebo |
|------------------------------------|---|---|---------|
| Number of subjects | 204 | 204 | 102 |
| Age categorical Units: Subjects | | | |

| | | | |
|---|----------------|----------------|----------------|
| Age continuous Units: years arithmetic mean standard deviation | 18.2 ± 1.87 | 18.2 ± 2.04 | 18.2 ± 2.03 |
| Gender categorical Units: subjects | | | |
| Female | 116 | 99 | 53 |
| Male | 88 | 105 | 49 |
| Baseline Pain Intensity by Categorical Scale | | | |
| Pain Intensity (PI) was rated by subjects on a 4-point Categorical Pain Intensity Scale (0 = no pain, 1 = mild pain, 2 = moderate pain, and 3 = severe pain). | | | |
| Units: Subjects | | | |
| Moderate pain | 83 | 74 | 42 |
| Severe pain | 121 | 130 | 60 |
| Baseline Pain by 11-Point Pain Intensity | | | |
| When subjects indicated at least moderate pain, they were asked to score their pain on the 11-Point Numerical Pain Intensity Rating Scale (0 = no pain, 10 = very painful). | | | |
| Units: scores on a scale arithmetic mean standard deviation | 7.9 ± 1.31 | 7.9 ± 1.3 | 7.9 ± 1.27 |

| Reporting group values | Total | | |
|------------------------------------|-------|--|--|
| Number of subjects | 510 | | |
| Age categorical Units: Subjects | | | |

| | | | |
|---|-----|--|--|
| Age continuous Units: years arithmetic mean standard deviation | - | | |
| Gender categorical Units: subjects | | | |
| Female | 268 | | |
| Male | 242 | | |
| Baseline Pain Intensity by Categorical Scale | | | |
| Pain Intensity (PI) was rated by subjects on a 4-point Categorical Pain Intensity Scale (0 = no pain, 1 = mild pain, 2 = moderate pain, and 3 = severe pain). | | | |
| Units: Subjects | | | |
| Moderate pain | 199 | | |
| Severe pain | 311 | | |
| Baseline Pain by 11-Point Pain Intensity | | | |
| When subjects indicated at least moderate pain, they were asked to score their pain on the 11-Point Numerical Pain Intensity Rating Scale (0 = no pain, 10 = very painful). | | | |
| Units: scores on a scale arithmetic mean standard deviation | - | | |

End points

End points reporting groups

| | |
|---|---|
| Reporting group title | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Reporting group description: Single oral dose of fast release aspirin tablet 1000 mg (2 x 500 mg) and 2 placebo-matching acetaminophen caplets with a full glass of water (240 milliliter [mL]) between 1-4 hours post dental surgery. | |
| Reporting group title | Acetaminophen (Tylenol extra strength) |
| Reporting group description: Single oral dose of acetaminophen (Tylenol extra strength) caplet 1000 mg (2 x 500 mg) and 2 placebo-matching aspirin tablets with a full glass of water (240 mL) between 1-4 hours post dental surgery. | |
| Reporting group title | Placebo |
| Reporting group description: Single oral dose of placebo (2 placebo aspirin tablets and 2 placebo acetaminophen caplets) with a full glass of water (240 mL) between 1-4 hours post dental surgery. | |
| Subject analysis set title | Intent-to-treat (ITT) population |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: ITT population included all randomized subjects who took at least 1 dose of the study drug and who had at least 1 post-dose assessment on an efficacy parameter. | |
| Subject analysis set title | Safety analysis set (SAF) population |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: SAF population included all randomized subjects who took at least 1 dose of the study drug. | |

Primary: Time to Meaningful Pain Relief (PR)

| | |
|--|-------------------------------------|
| End point title | Time to Meaningful Pain Relief (PR) |
| End point description: Meaningful pain relief was defined as when the subject felt the degree of pain relief was meaningful to them. Time to meaningful pain relief was determined by a double-stopwatch measurement using Kaplan-Meier estimate, provided that the subject experienced both "perceptible" and "meaningful" pain relief. Those subjects who do not achieve meaningful pain relief after 6 hours after dosing or those who took rescue medication before experiencing meaningful pain relief was censored in the analysis. '99999' in the below table indicates, the median time to meaningful PR could not be calculated for the placebo group due to timing and number of censored observations. | |
| End point type | Primary |
| End point timeframe: 0 to 6 hours | |

| End point values | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) | Acetaminophen (Tylenol extra strength) | Placebo | |
|----------------------------------|---|--|------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 204 ^[1] | 204 ^[2] | 102 ^[3] | |
| Units: minutes | | | | |
| median (confidence interval 95%) | 42.3 (38.8 to 46.5) | 42.9 (38.8 to 48.18) | 99999 (99999 to 99999) | |

Notes:

[1] - ITT population.

[2] - ITT population.

[3] - ITT population.

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Statistical analysis 1 |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.945 |
| Method | Logrank |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 2 |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Logrank |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 3 |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Logrank |

Secondary: Time to First Perceptible Pain Relief

| | |
|---|---------------------------------------|
| End point title | Time to First Perceptible Pain Relief |
| End point description: The double-stopwatch method was used to record time to first perceptible PR. Time to first perceptible PR was defined as the duration from the subject taking the study drug until the subject first began to feel any pain-relieving effect from the study drug. | |
| End point type | Secondary |
| End point timeframe: 0 to 6 hours | |

| End point values | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) | Acetaminophen (Tylenol extra strength) | Placebo | |
|----------------------------------|---|--|--------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 204 ^[4] | 204 ^[5] | 102 ^[6] | |
| Units: minutes | | | | |
| median (confidence interval 95%) | 17.2 (15 to 19.1) | 15 (14.63 to 16.07) | 27.3 (20 to 35) | |

Notes:

[4] - ITT population

[5] - ITT population

[6] - ITT population

Statistical analyses

| Statistical analysis title | Statistical analysis 1 |
|---|--|
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.392 |
| Method | Logrank |

| Statistical analysis title | Statistical analysis 2 |
|---|---|
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Logrank |

| Statistical analysis title | Statistical analysis 3 |
|---|--|
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Logrank |

Secondary: Time to First Perceptible Pain Relief Confirmed

| | |
|---|---|
| End point title | Time to First Perceptible Pain Relief Confirmed |
| End point description: The double-stopwatch method was used to record time to first perceptible PR confirmed. Time to first perceptible PR confirmed was defined as the duration from the subject taking the study drug until the first stopwatch was stopped as long as the subject stopped the second stopwatch at some later time or recorded either a PR score of at least 1 or a Pain Intensity Difference (PID) score of at least 1 at the next time point assessment. | |
| End point type | Secondary |
| End point timeframe: 0 to 6 hours | |

| End point values | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) | Acetaminophen (Tylenol extra strength) | Placebo | |
|----------------------------------|---|--|-----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 204 ^[7] | 204 ^[8] | 102 ^[9] | |
| Units: minutes | | | | |
| median (confidence interval 95%) | 17.3 (15.67 to 19.15) | 15.4 (14.67 to 16.22) | 27.5 (20.97 to 35.28) | |

Notes:

[7] - ITT population

[8] - ITT population

[9] - ITT population

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Statistical analysis 1 |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.355 |
| Method | Logrank |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 2 |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Logrank |

| | |
|--|------------------------|
| | Statistical analysis 3 |
|--|------------------------|

| | |
|---|--|
| Statistical analysis title | |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Logrank |

Secondary: Pain Intensity at 5, 10, 15, 20, 25, 30, 35, 40, 50, and 60 minutes and at 1.5, 2, 3, 4, 5, and 6 hours After Dosing

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|-----------------|--|
| End point title | Pain Intensity at 5, 10, 15, 20, 25, 30, 35, 40, 50, and 60 minutes and at 1.5, 2, 3, 4, 5, and 6 hours After Dosing |
|-----------------|--|

End point description:

Pain intensity was evaluated using a 4-point categorical Pain Intensity Rating Scale (0 = no pain, 1 = mild pain, 2 = moderate pain, 3 = severe pain) for all pain intensity assessments post-dose.

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

End point timeframe:

5, 10, 15, 20, 25, 30, 35, 40, and 50 minutes and 1, 1.5, 2, 3, 4, 5, and 6 hours post-dose

| End point values | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) | Acetaminophen (Tylenol extra strength) | Placebo | |
|-----------------------------|---|--|---------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 204 ^[10] | 204 ^[11] | 102 ^[12] | |
| Units: subjects | | | | |
| 5 minutes: No pain | 0 | 0 | 0 | |
| 5 minutes: Mild pain | 4 | 3 | 2 | |
| 5 minutes: Moderate pain | 79 | 78 | 38 | |
| 5 minutes: Severe pain | 121 | 123 | 62 | |
| 10 minutes: No pain | 0 | 1 | 0 | |
| 10 minutes: Mild pain | 7 | 8 | 6 | |
| 10 minutes: Moderate pain | 84 | 83 | 34 | |
| 10 minutes: Severe pain | 113 | 112 | 62 | |
| 15 minutes: No pain | 1 | 2 | 0 | |
| 15 minutes: Mild pain | 12 | 19 | 7 | |
| 15 minutes: Moderate pain | 89 | 91 | 35 | |
| 15 minutes: Severe pain | 102 | 92 | 60 | |
| 20 minutes: No pain | 7 | 3 | 0 | |
| 20 minutes: Mild pain | 30 | 38 | 8 | |
| 20 minutes: Moderate pain | 96 | 94 | 37 | |
| 20 minutes: Severe pain | 71 | 69 | 57 | |
| 25 minutes: No pain | 12 | 7 | 0 | |
| 25 minutes: Mild pain | 47 | 59 | 8 | |
| 25 minutes: Moderate pain | 102 | 83 | 36 | |
| 25 minutes: Severe pain | 43 | 55 | 58 | |
| 30 minutes: No pain | 18 | 16 | 0 | |
| 30 minutes: Mild pain | 70 | 81 | 10 | |

| | | | | |
|---------------------------|-----|-----|----|--|
| 30 minutes: Moderate pain | 84 | 66 | 40 | |
| 30 minutes: Severe pain | 32 | 41 | 52 | |
| 35 minutes: No pain | 24 | 22 | 1 | |
| 35 minutes: Mild pain | 90 | 84 | 7 | |
| 35 minutes: Moderate pain | 65 | 69 | 40 | |
| 35 minutes: Severe pain | 25 | 29 | 54 | |
| 40 minutes: No pain | 32 | 36 | 1 | |
| 40 minutes: Mild pain | 101 | 85 | 8 | |
| 40 minutes: Moderate pain | 48 | 61 | 39 | |
| 40 minutes: Severe pain | 23 | 22 | 54 | |
| 50 minutes: No pain | 46 | 45 | 1 | |
| 50 minutes: Mild pain | 103 | 93 | 8 | |
| 50 minutes: Moderate pain | 38 | 51 | 40 | |
| 50 minutes: Severe pain | 17 | 15 | 53 | |
| 1 hour: No Pain | 59 | 52 | 1 | |
| 1 hour: Mild Pain | 99 | 100 | 12 | |
| 1 hour: Moderate Pain | 30 | 39 | 38 | |
| 1 hour: Severe Pain | 16 | 13 | 51 | |
| 1.5 hour: No Pain | 62 | 63 | 1 | |
| 1.5 hour: Mild Pain | 94 | 96 | 13 | |
| 1.5 hour: Moderate Pain | 27 | 27 | 32 | |
| 1.5 hour: Severe Pain | 21 | 18 | 56 | |
| 2 hours: No Pain | 49 | 59 | 1 | |
| 2 hours: Mild Pain | 84 | 101 | 15 | |
| 2 hours: Moderate Pain | 42 | 22 | 22 | |
| 2 hours: Severe Pain | 29 | 22 | 64 | |
| 3 hours: No Pain | 30 | 46 | 7 | |
| 3 hours: Mild Pain | 83 | 99 | 15 | |
| 3 hours: Moderate Pain | 45 | 30 | 14 | |
| 3 hours: Severe Pain | 46 | 29 | 66 | |
| 4 hours: No Pain | 29 | 54 | 9 | |
| 4 hours: Mild Pain | 69 | 88 | 15 | |
| 4 hours: Moderate Pain | 48 | 29 | 12 | |
| 4 hours: Severe Pain | 58 | 33 | 66 | |
| 5 hours: No Pain | 21 | 49 | 12 | |
| 5 hours: Mild Pain | 66 | 87 | 10 | |
| 5 hours: Moderate Pain | 53 | 30 | 13 | |
| 5 hours: Severe Pain | 64 | 38 | 67 | |
| 6 hours: No Pain | 19 | 37 | 11 | |
| 6 hours: Mild Pain | 59 | 76 | 10 | |
| 6 hours: Moderate Pain | 52 | 41 | 14 | |
| 6 hours: Severe Pain | 74 | 50 | 67 | |

Notes:

[10] - ITT population

[11] - ITT population

[12] - ITT population`

Statistical analyses

| | |
|-----------------------------------|--|
| Statistical analysis title | Statistical analysis 1: 5 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.812 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 2: 5 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.81 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 3: 5 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.961 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 4: 10 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.853 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 5: 10 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.5 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 6: 10 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.415 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 7: 15 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.202 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 8: 15 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.195 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 9: 15 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.024 |
| Method | Cochran-Mantel-Haenszel |

| | |
|-----------------------------------|--|
| Statistical analysis title | Statistical analysis 10: 20 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.754 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 11: 20 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 12: 20 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 13: 25 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.656 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 14: 25 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 15: 25 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 16: 30 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.941 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 17: 30 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 18: 30 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|-----------------------------------|---|
| Statistical analysis title | Statistical analysis 19: 35 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.414 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 20: 35 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 21: 35 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 22: 40 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.596 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 23: 40 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 24: 40 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 25: 50 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.473 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 26: 50 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 27: 50 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|-----------------------------------|---|
| Statistical analysis title | Statistical analysis 28: 1 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.43 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 29: 1 hour post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 30: 1 hour post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 31: 1.5 hours post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.765 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 32: 1.5 hours post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 33: 1.5 hours post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 34: 2 hours post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.019 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 35: 2 hours post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 36: 2 hours post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|-----------------------------------|---|
| Statistical analysis title | Statistical analysis 37: 3 hours post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 38: 3 hours post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 39: 3 hours post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 40: 4 hours post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 41: 4 hours post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 42: 4 hours post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 43: 5 hours post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 44: 5 hours post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 45: 5 hours post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|-----------------------------------|---|
| Statistical analysis title | Statistical analysis 46: 6 hours post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 47: 6 hours post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 48: 6 hours post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Pain Relief at 5, 10, 15, 20, 25, 30, 35, 40, 50, and 60 minutes and at 1.5, 2, 3, 4, 5, and 6 hours After Dosing

| | |
|-----------------|---|
| End point title | Pain Relief at 5, 10, 15, 20, 25, 30, 35, 40, 50, and 60 minutes and at 1.5, 2, 3, 4, 5, and 6 hours After Dosing |
|-----------------|---|

End point description:

Subjects rated pain relief on a 5-point categorical Pain Relief Rating Scale (0 = no relief, 1 = a little relief, 2 = some relief, 3 = a lot of relief, 4 = complete relief).

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

End point timeframe:

5, 10, 15, 20, 25, 30, 35, 40, and 50 minutes and 1, 1.5, 2, 3, 4, 5, and 6 hours After Dosing

| End point values | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) | Acetaminophen (Tylenol extra strength) | Placebo | |
|-----------------------------|---|--|---------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 204 ^[13] | 204 ^[14] | 102 ^[15] | |
| Units: subjects | | | | |
| 5 minutes: No relief | 171 | 167 | 87 | |
| 5 minutes: Little relief | 30 | 32 | 14 | |

| | | | |
|-----------------------------|-----|-----|----|
| 5 minutes: Some relief | 3 | 5 | 1 |
| 5 minutes: Lot of relief | 0 | 0 | 0 |
| 5 minutes: Complete relief | 0 | 0 | 0 |
| 10 minutes: No relief | 152 | 135 | 81 |
| 10 minutes: Little relief | 39 | 57 | 17 |
| 10 minutes: Some relief | 12 | 11 | 4 |
| 10 minutes: Lot of relief | 1 | 1 | 0 |
| 10 minutes: Complete relief | 0 | 0 | 0 |
| 15 minutes: No relief | 113 | 96 | 73 |
| 15 minutes: Little relief | 67 | 77 | 23 |
| 15 minutes: Some relief | 18 | 22 | 5 |
| 15 minutes: Lot of relief | 6 | 7 | 1 |
| 15 minutes: Complete relief | 0 | 2 | 0 |
| 20 minutes: No relief | 67 | 60 | 63 |
| 20 minutes: Little relief | 84 | 67 | 29 |
| 20 minutes: Some relief | 37 | 55 | 8 |
| 20 minutes: Lot of relief | 10 | 19 | 2 |
| 20 minutes: Complete relief | 6 | 3 | 0 |
| 25 minutes: No relief | 38 | 40 | 57 |
| 25 minutes: Little relief | 66 | 64 | 31 |
| 25 minutes: Some relief | 65 | 49 | 12 |
| 25 minutes: Lot of relief | 24 | 44 | 2 |
| 25 minutes: Complete relief | 11 | 7 | 0 |
| 30 minutes: No relief | 24 | 23 | 50 |
| 30 minutes: Little relief | 51 | 56 | 35 |
| 30 minutes: Some relief | 66 | 50 | 15 |
| 30 minutes: Lot of relief | 45 | 59 | 2 |
| 30 minutes: Complete relief | 18 | 16 | 0 |
| 35 minutes: No relief | 17 | 17 | 43 |
| 35 minutes: Little relief | 41 | 43 | 42 |
| 35 minutes: Some relief | 48 | 57 | 15 |
| 35 minutes: Lot of relief | 74 | 65 | 1 |
| 35 minutes: Complete relief | 24 | 22 | 1 |
| 40 minutes: No relief | 14 | 14 | 42 |
| 40 minutes: Little relief | 34 | 34 | 39 |
| 40 minutes: Some relief | 38 | 54 | 17 |
| 40 minutes: Lot of relief | 86 | 66 | 3 |
| 40 minutes: Complete relief | 32 | 36 | 1 |
| 50 minutes: No relief | 12 | 10 | 46 |
| 50 minutes: Little relief | 20 | 24 | 33 |
| 50 minutes: Some relief | 38 | 50 | 18 |
| 50 minutes: Lot of relief | 88 | 75 | 4 |
| 50 minutes: Complete relief | 46 | 45 | 1 |
| 1 hour: No relief | 11 | 8 | 47 |
| 1 hour: Little relief | 15 | 21 | 25 |
| 1 hour: Some relief | 35 | 48 | 24 |
| 1 hour: Lot of relief | 84 | 75 | 5 |
| 1 hour: Complete relief | 59 | 52 | 1 |
| 1.5 hour: No relief | 21 | 18 | 60 |
| 1.5 hour: Little relief | 13 | 7 | 15 |
| 1.5 hour: Some relief | 30 | 39 | 13 |
| 1.5 hour: Lot of relief | 77 | 78 | 13 |

| | | | | |
|---------------------------|-----|----|----|--|
| 1.5 hour: Complete relief | 63 | 62 | 1 | |
| 2 hours: No relief | 35 | 24 | 73 | |
| 2 hours: Little relief | 11 | 12 | 4 | |
| 2 hours: Some relief | 46 | 23 | 11 | |
| 2 hours: Lot of relief | 63 | 87 | 13 | |
| 2 hours: Complete relief | 49 | 58 | 1 | |
| 3 hours: No relief | 53 | 32 | 74 | |
| 3 hours: Little relief | 22 | 10 | 2 | |
| 3 hours: Some relief | 40 | 32 | 11 | |
| 3 hours: Lot of relief | 60 | 84 | 8 | |
| 3 hours: Complete relief | 29 | 46 | 7 | |
| 4 hours: No relief | 75 | 38 | 74 | |
| 4 hours: Little relief | 12 | 6 | 3 | |
| 4 hours: Some relief | 39 | 30 | 6 | |
| 4 hours: Lot of relief | 49 | 76 | 10 | |
| 4 hours: Complete relief | 29 | 54 | 9 | |
| 5 hours: No relief | 90 | 45 | 76 | |
| 5 hours: Little relief | 14 | 13 | 2 | |
| 5 hours: Some relief | 21 | 22 | 5 | |
| 5 hours: Lot of relief | 58 | 75 | 7 | |
| 5 hours: Complete relief | 21 | 49 | 12 | |
| 6 hours: No relief | 102 | 55 | 76 | |
| 6 hours: Little relief | 14 | 13 | 2 | |
| 6 hours: Some relief | 17 | 26 | 4 | |
| 6 hours: Lot of relief | 52 | 73 | 9 | |
| 6 hours: Complete relief | 19 | 37 | 11 | |

Notes:

[13] - ITT population

[14] - ITT population

[15] - ITT population

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Statistical analysis 1: 5 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.577 |
| Method | Cochran-Mantel-Haenszel |

| | |
|-----------------------------------|---|
| Statistical analysis title | Statistical analysis 2: 5 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.73 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 3: 5 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.429 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 4: 10 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.093 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 5: 10 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.315 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 6: 10 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.019 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 7: 15 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.083 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 8: 15 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.005 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 9: 15 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 10: 20 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.064 |
| Method | Cochran-Mantel-Haenszel |

| | |
|-----------------------------------|--|
| Statistical analysis title | Statistical analysis 11: 20 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 12: 20 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 13: 25 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.64 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 14: 25 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 15: 25 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 16: 30 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.725 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 17: 30 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 18: 30 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 19: 35 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.456 |
| Method | Cochran-Mantel-Haenszel |

| | |
|-----------------------------------|--|
| Statistical analysis title | Statistical analysis 20: 35 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 21: 35 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 22: 40 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.51 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 23: 40 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 24: 40 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 25: 50 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.392 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 26: 50 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 27: 50 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 28: 1 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.19 |
| Method | Cochran-Mantel-Haenszel |

| | |
|-----------------------------------|--|
| Statistical analysis title | Statistical analysis 29: 1 hour post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 30: 1 hour post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 31: 1.5 hours post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.878 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 32: 1.5 hours post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 33: 1.5 hours post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 34: 2 hours post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.013 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 35: 2 hours post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 36: 2 hours post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 37: 3 hours post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|-----------------------------------|--|
| Statistical analysis title | Statistical analysis 38: 3 hours post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 39: 3 hours post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 40: 4 hours post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 41: 4 hours post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 42: 4 hours post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 43: 5 hours post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 44: 5 hours post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 45: 5 hours post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 46: 6 hours post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|-----------------------------------|--|
| Statistical analysis title | Statistical analysis 47: 6 hours post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 48: 6 hours post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Pain Intensity Difference (PID) at 5, 10, 15, 20, 25, 30, 35, 40, 50, and 60 minutes and at 1.5, 2, 3, 4, 5, and 6 hours After Dosing

| | |
|-----------------|---|
| End point title | Pain Intensity Difference (PID) at 5, 10, 15, 20, 25, 30, 35, 40, 50, and 60 minutes and at 1.5, 2, 3, 4, 5, and 6 hours After Dosing |
|-----------------|---|

End point description:

Pain intensity was evaluated using a 4-point Categorical Pain Intensity Rating Scale (0 = no pain, 1 = mild pain, 2 = moderate pain, 3 = severe pain) for all pain intensity assessments post-dose. For each post-dose time point, PID was derived by subtracting the pain intensity at the post-dose time point from the baseline intensity score (baseline score – post-baseline score). A positive difference was indicative of improvement.

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

End point timeframe:

5, 10, 15, 20, 25, 30, 35, 40, and 50 minutes and 1, 1.5, 2, 3, 4, 5, and 6 hours

| End point values | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) | Acetaminophen (Tylenol extra strength) | Placebo | |
|--------------------------------------|---|--|---------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 204 ^[16] | 204 ^[17] | 102 ^[18] | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| 5 Minutes Post-dose | 0 (± 0.31) | 0 (± 0.22) | 0 (± 0.37) | |
| 10 Minutes Post-dose | 0.1 (± 0.41) | 0.1 (± 0.39) | 0 (± 0.51) | |
| 15 Minutes Post-dose | 0.2 (± 0.5) | 0.3 (± 0.55) | 0.1 (± 0.51) | |
| 20 Minutes Post-dose | 0.5 (± 0.73) | 0.5 (± 0.66) | 0.1 (± 0.54) | |
| 25 Minutes Post-dose | 0.7 (± 0.8) | 0.7 (± 0.77) | 0.1 (± 0.57) | |
| 30 Minutes Post-dose | 1 (± 0.83) | 1 (± 0.87) | 0.2 (± 0.65) | |
| 35 Minutes Post-dose | 1.1 (± 0.88) | 1.1 (± 0.86) | 0.1 (± 0.64) | |
| 40 Minutes Post-dose | 1.3 (± 0.91) | 1.3 (± 0.87) | 0.2 (± 0.7) | |
| 50 Minutes Post-dose | 1.5 (± 0.92) | 1.5 (± 0.88) | 0.2 (± 0.73) | |

| | | | | |
|---------------------|--------------|--------------|--------------|--|
| 1 Hour Post-dose | 1.6 (± 0.93) | 1.6 (± 0.82) | 0.2 (± 0.77) | |
| 1.5 Hours Post-dose | 1.6 (± 0.98) | 1.6 (± 0.93) | 0.2 (± 0.85) | |
| 2 Hours Post-dose | 1.3 (± 1.05) | 1.6 (± 0.97) | 0.1 (± 0.88) | |
| 3 Hours Post-dose | 1.1 (± 1.04) | 1.4 (± 0.98) | 0.2 (± 1.05) | |
| 4 Hours Post-dose | 0.9 (± 1.07) | 1.4 (± 1.05) | 0.3 (± 1.13) | |
| 5 Hours Post-dose | 0.8 (± 1.03) | 1.4 (± 1.04) | 0.3 (± 1.17) | |
| 6 Hours Post-dose | 0.7 (± 1) | 1.1 (± 1.02) | 0.2 (± 1.16) | |

Notes:

[16] - ITT population

[17] - ITT population

[18] - ITT population

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Statistical analysis 1: 5 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.378 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 2: 5 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.586 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 3: 5 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.206 |
| Method | ANCOVA |

| | |
|-----------------------------------|--|
| Statistical analysis title | Statistical analysis 4: 10 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|---------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.165 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 5: 10 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.505 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 6: 10 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.072 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 7: 15 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.012 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 8: 15 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.141 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 9: 15 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 10: 20 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.52 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 11: 20 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 12: 20 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|-----------------------------------|---|
| Statistical analysis title | Statistical analysis 13: 25 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|---------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.77 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 14: 25 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 15: 25 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 16: 30 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.844 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 17: 30 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 18: 30 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 19: 35 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.553 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 20: 35 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 21: 35 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|-----------------------------------|---|
| Statistical analysis title | Statistical analysis 22: 40 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|---------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.858 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 23: 40 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 24: 40 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 25: 50 minutes post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.672 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 26: 50 minutes post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 27: 50 minutes post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 28: 1 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.694 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 29: 1 hour post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 30: 1 hour post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|-----------------------------------|---|
| Statistical analysis title | Statistical analysis 31: 1.5 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|---------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.585 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 32: 1.5 hour post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 33: 1.5 hour post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 34: 2 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.013 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 35: 2 hour post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 36: 2 hour post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 37: 3 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 38: 3 hour post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 39: 3 hour post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|-----------------------------------|---|
| Statistical analysis title | Statistical analysis 40: 4 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|---------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 41: 4 hour post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 42: 4 hour post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 43: 5 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 44: 5 hour post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 45: 5 hour post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 46: 6 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 47: 6 hour post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 48: 6 hour post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|--|--|
| Secondary: Summed Pain Intensity Differences (SPID) from Hour 0 through Hour 2, Hour 4 and Hour 6 | |
| End point title | Summed Pain Intensity Differences (SPID) from Hour 0 through Hour 2, Hour 4 and Hour 6 |

End point description:

Pain intensity was evaluated using a 4-point categorical Pain Intensity Rating Scale (0 = no pain, 1 = mild pain, 2 = moderate pain, 3 = severe pain) for all pain intensity assessments post-dose. Time weighted SPID was calculated by multiplying the PID score at each post-dose time point by the duration (in hours) since the preceding time point and then summing these values for 0-2, 0-4, 0-6 hour intervals, respectively. The possible total score ranges of SPIDs are: SPID0-2: 0 to 6, SPID0-4: 0 to 12, SPID0-6: 0 to 18. The higher the SPID value, the more improvement of pain relief.

| | |
|-----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| 0 - 6 hours post-dose | |

| End point values | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) | Acetaminophen (Tylenol extra strength) | Placebo | |
|--------------------------------------|---|--|---------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 204 ^[19] | 204 ^[20] | 102 ^[21] | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| SPID 0 - 2 | 2.4 (± 1.5) | 2.6 (± 1.4) | 0.3 (± 1.28) | |
| SPID 0 - 4 | 4.4 (± 3.34) | 5.4 (± 3.18) | 0.8 (± 3.31) | |
| SPID 0 - 6 | 5.9 (± 5.09) | 7.9 (± 4.94) | 1.3 (± 5.54) | |

Notes:

[19] - ITT population

[20] - ITT population

[21] - ITT population

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Statistical analysis 1: SPID 0-2 |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.267 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 2: SPID 0-2 |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 3: SPID 0-2 |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 4: SPID 0-4 |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.002 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 5: SPID 0-4 |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 6: SPID 0-4 |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|-----------------------------------|--|
| Statistical analysis title | Statistical analysis 7: SPID 0-6 |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|---------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 8: SPID 0-6 |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 9: SPID 0-6 |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

Secondary: Summed Total Pain Relief (TOTPAR) from Hour 0 through Hour 2, Hour 4 and Hour 6

| | |
|-----------------|---|
| End point title | Summed Total Pain Relief (TOTPAR) from Hour 0 through Hour 2, Hour 4 and Hour 6 |
|-----------------|---|

End point description:

Subjects rated pain relief on a 5-point categorical Pain Relief Rating Scale (0 = no relief, 1 = a little relief, 2 = some relief, 3 = a lot of relief, 4 = complete relief). TOTPAR was calculated by multiplying the pain relief score at each post-dose time point by the duration (in hours) since the preceding time point and then summing these values. The possible total score ranges of TOTPARs are: TOTPAR0-2: 0 to 6, TOTPAR0-4: 0 to 12, TOTPAR0-6: 0 to 18. The higher the LS Means scores, the more pain relief was obtained.

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

End point timeframe:

0 to 6 hours post-dose

| End point values | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) | Acetaminophen (Tylenol extra strength) | Placebo | |
|--------------------------------------|---|--|---------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 204 ^[22] | 204 ^[23] | 102 ^[24] | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| TOTPAR 0 - 2 | 4.3 (± 1.94) | 4.5 (± 1.83) | 1.4 (± 1.6) | |
| TOTPAR 0 - 4 | 8 (± 4.43) | 9.5 (± 4.18) | 3 (± 4.07) | |
| TOTPAR 0 - 6 | 11 (± 7.04) | 14 (± 6.73) | 4.5 (± 6.82) | |

Notes:

[22] - ITT population

[23] - ITT population

[24] - ITT population

Statistical analyses

| Statistical analysis title | Statistical analysis 1: TOTPAR 0-2 |
|---|--|
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.283 |
| Method | ANCOVA |

| Statistical analysis title | Statistical analysis 2: TOTPAR 0-2 |
|---|---|
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| Statistical analysis title | Statistical analysis 3: TOTPAR 0-2 |
|---|--|
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| Statistical analysis title | Statistical analysis 4: TOTPAR 0-4 |
|-----------------------------------|---|
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid |

| | |
|---|------------------------------------|
| | (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 5: TOTPAR 0-4 |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 6: TOTPAR 0-4 |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 7: TOTPAR 0-6 |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|-----------------------------------|--|
| Statistical analysis title | Statistical analysis 8: TOTPAR 0-6 |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|---------------|
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 9: TOTPAR 0-6 |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

Secondary: Time to First use of Rescue Medication

| | |
|---|--|
| End point title | Time to First use of Rescue Medication |
| End point description: Time to first use of rescue medication was estimated using the Kaplan-Meier method and analyzed by a log rank test stratified by trial site and baseline pain intensity (PI). The criteria were if adequate pain relief was not achieved, then subjects were permitted to take rescue medication. '99999' in the below table indicates data was not analysed due to timing and number of censored observations. | |
| End point type | Secondary |
| End point timeframe: 0 to 6 hours | |

| End point values | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) | Acetaminophen (Tylenol extra strength) | Placebo | |
|----------------------------------|---|--|---------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 204 ^[25] | 204 ^[26] | 102 ^[27] | |
| Units: hours | | | | |
| median (confidence interval 95%) | 99999 (320 to 99999) | 99999 (99999 to 99999) | 97.5 (81 to 104) | |

Notes:

[25] - ITT population

[26] - ITT population

[27] - ITT population

Statistical analyses

| | |
|-----------------------------------|--|
| Statistical analysis title | Statistical analysis 1 |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|---------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Logrank |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 2 |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Logrank |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 3 |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Logrank |

Secondary: Cumulative Percentage of Subjects Taking Rescue Medication

| | |
|------------------------|---|
| End point title | Cumulative Percentage of Subjects Taking Rescue Medication |
| End point description: | The cumulative percentage taking rescue medication by time point was analyzed using Chi-square tests. |
| End point type | Secondary |
| End point timeframe: | 1, 2, 3, 4, 5, and 6 hours post-dose |

| End point values | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) | Acetaminophen (Tylenol extra strength) | Placebo | |
|-------------------------------|---|--|---------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 204 ^[28] | 204 ^[29] | 102 ^[30] | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| 1 hour post-dose | 0 | 0 | 0 | |
| 2 hour post-dose | 12.3 | 8.8 | 64.7 | |
| 3 hour post-dose | 17.6 | 14.2 | 70.6 | |

| | | | | |
|------------------|------|------|------|--|
| 4 hour post-dose | 33.3 | 16.7 | 70.6 | |
| 5 hour post-dose | 41.2 | 21.6 | 74.5 | |
| 6 hour post-dose | 46.1 | 25 | 74.5 | |

Notes:

[28] - ITT population

[29] - ITT population

[30] - ITT population

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Statistical analysis 1: 2 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.259 |
| Method | Chi-squared |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 2: 2 hour post-dose |
| Comparison groups | Placebo v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Chi-squared |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 3: 2 hour post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Chi-squared |

| | |
|-----------------------------------|---|
| Statistical analysis title | Statistical analysis 4: 3 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicyclic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|---------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.344 |
| Method | Chi-squared |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 5: 3 hour post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Chi-squared |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 6: 3 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Placebo |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Chi-squared |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 7: 4 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Chi-squared |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 8: 4 hour post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Chi-squared |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 9: 4 hour post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Chi-squared |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 10: 5 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Chi-squared |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 11: 5 hour post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Chi-squared |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 12: 5 hour post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Chi-squared |

| | |
|-----------------------------------|--|
| Statistical analysis title | Statistical analysis 13: 6 hour post-dose |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |

| | |
|---|---------------|
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Chi-squared |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 14: 6 hour post-dose |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Chi-squared |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 15: 6 hour post-dose |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Chi-squared |

Secondary: Global Assessment of the Investigational Product as a Pain Reliever at 6 hours After Dosing or Immediately Before the First Intake of Rescue Medication

| | |
|-----------------|---|
| End point title | Global Assessment of the Investigational Product as a Pain Reliever at 6 hours After Dosing or Immediately Before the First Intake of Rescue Medication |
|-----------------|---|

End point description:

Global assessment of the study drug as a pain reliever was analyzed using the Cochran-Mantel-Haenszel (CMH) test with modified ridit scores. Categorical Scale: Poor (0), Fair (1), Good (2), Very Good (3), Excellent (4).

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

End point timeframe:

At 6 hours postdose or immediately before first use of rescue medication

| | | | | |
|-----------------------------|---|--|---------------------|--|
| End point values | Acetylsalicylic acid (Fast release Aspirin, BAY1019036) | Acetaminophen (Tylenol extra strength) | Placebo | |
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 204 ^[31] | 204 ^[32] | 102 ^[33] | |
| Units: subjects | | | | |

| | | | | |
|-----------|----|----|----|--|
| Poor | 25 | 11 | 60 | |
| Fair | 19 | 25 | 17 | |
| Good | 48 | 36 | 16 | |
| Very good | 82 | 96 | 7 | |
| Excellent | 30 | 36 | 2 | |

Notes:

[31] - ITT population

[32] - ITT population

[33] - ITT population

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Statistical analysis 1 |
| Comparison groups | Acetaminophen (Tylenol extra strength) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 408 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.051 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical analysis 2 |
| Comparison groups | Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 3 |
| Comparison groups | Placebo v Acetaminophen (Tylenol extra strength) |
| Number of subjects included in analysis | 306 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were recorded throughout the treatment period through 5 days after investigational product administration. All serious adverse events were collected through about 30 days after the last dose of investigational product or placebo.

Adverse event reporting additional description:

A treatment-emergent adverse event was defined as any adverse event that began after study drug administration, or any ongoing event that worsened in severity after study drug administration.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 14.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------------------|
| Reporting group title | Tylenol Extra Strength |
|-----------------------|------------------------|

Reporting group description:

Single oral dose of acetaminophen (Tylenol extra strength) caplet 1000 mg (2 x 500 mg) and 2 placebo-matching aspirin tablets with a full glass of water (240 mL) between 1-4 hours post dental surgery.

| | |
|-----------------------|----------------------|
| Reporting group title | Aspirin (BAY1019036) |
|-----------------------|----------------------|

Reporting group description:

Single oral dose of fast release aspirin tablet 1000 milligram (mg) (2 x 500 mg) and 2 placebo-matching acetaminophen caplets with a full glass of water (240 mL) between 1-4 hours post dental surgery.

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Single oral dose of placebo (2 placebo-matching aspirin tablets and 2 placebo-matching acetaminophen caplets) with a full glass of water (240 mL) between 1-4 hours post dental surgery.

| Serious adverse events | Tylenol Extra Strength | Aspirin (BAY1019036) | Placebo |
|---|------------------------|----------------------|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 204 (0.00%) | 0 / 204 (0.00%) | 0 / 102 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | Tylenol Extra Strength | Aspirin (BAY1019036) | Placebo |
|---|------------------------|----------------------|-------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 22 / 204 (10.78%) | 20 / 204 (9.80%) | 18 / 102 (17.65%) |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|--|--|--|
| Joint dislocation subjects affected / exposed occurrences (all) | 0 / 204 (0.00%) 0 | 0 / 204 (0.00%) 0 | 1 / 102 (0.98%) 1 |
| Vascular disorders Haemorrhage subjects affected / exposed occurrences (all) | 2 / 204 (0.98%) 2 | 0 / 204 (0.00%) 0 | 0 / 102 (0.00%) 0 |
| Cardiac disorders Palpitations subjects affected / exposed occurrences (all) | 0 / 204 (0.00%) 0 | 0 / 204 (0.00%) 0 | 1 / 102 (0.98%) 1 |
| Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Paraesthesia subjects affected / exposed occurrences (all) | 1 / 204 (0.49%) 1 2 / 204 (0.98%) 2 1 / 204 (0.49%) 1 | 0 / 204 (0.00%) 0 4 / 204 (1.96%) 4 0 / 204 (0.00%) 0 | 4 / 102 (3.92%) 4 3 / 102 (2.94%) 3 0 / 102 (0.00%) 0 |
| General disorders and administration site conditions Feeling hot subjects affected / exposed occurrences (all) | 1 / 204 (0.49%) 1 | 0 / 204 (0.00%) 0 | 0 / 102 (0.00%) 0 |
| Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all) | 0 / 204 (0.00%) 0 | 1 / 204 (0.49%) 1 | 0 / 102 (0.00%) 0 |
| Eye disorders Vision blurred subjects affected / exposed occurrences (all) | 1 / 204 (0.49%) 1 | 0 / 204 (0.00%) 0 | 1 / 102 (0.98%) 1 |
| Gastrointestinal disorders Abdominal pain upper subjects affected / exposed occurrences (all) Diarrhoea | 0 / 204 (0.00%) 0 | 1 / 204 (0.49%) 1 | 0 / 102 (0.00%) 0 |

| | | | |
|---|------------------|------------------|------------------|
| subjects affected / exposed | 0 / 204 (0.00%) | 1 / 204 (0.49%) | 0 / 102 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 204 (0.49%) | 0 / 204 (0.00%) | 0 / 102 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypoaesthesia oral | | | |
| subjects affected / exposed | 0 / 204 (0.00%) | 1 / 204 (0.49%) | 0 / 102 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nausea | | | |
| subjects affected / exposed | 16 / 204 (7.84%) | 11 / 204 (5.39%) | 10 / 102 (9.80%) |
| occurrences (all) | 16 | 11 | 10 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 204 (0.00%) | 1 / 204 (0.49%) | 0 / 102 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 9 / 204 (4.41%) | 8 / 204 (3.92%) | 4 / 102 (3.92%) |
| occurrences (all) | 9 | 8 | 4 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 204 (0.00%) | 1 / 204 (0.49%) | 0 / 102 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 204 (0.00%) | 0 / 204 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Hypoaesthesia facial | | | |
| subjects affected / exposed | 0 / 204 (0.00%) | 1 / 204 (0.49%) | 0 / 102 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 204 (0.00%) | 0 / 204 (0.00%) | 3 / 102 (2.94%) |
| occurrences (all) | 0 | 0 | 3 |
| Rash | | | |
| subjects affected / exposed | 1 / 204 (0.49%) | 0 / 204 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all) | 1 | 0 | 1 |
| Infections and infestations | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Alveolar osteitis | | | |
| subjects affected / exposed | 1 / 204 (0.49%) | 0 / 204 (0.00%) | 1 / 102 (0.98%) |
| occurrences (all) | 1 | 0 | 1 |

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.

| |
|--|
| '99999' in the posting indicates that data was not available. Decimal places were automatically truncated if last decimal equals zero. |
|--|

Notes: