



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
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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	Investigator, Data analyst, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Acetylsalicylic 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	Acetylsalicylic 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)
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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
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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)
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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)
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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
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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 Male	116 88	99 105	53 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 Severe pain	83 121	74 130	42 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			
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End points

End points reporting groups

Reporting group title	Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
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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)
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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
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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
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Subject analysis set type	Intention-to-treat
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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
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Subject analysis set type	Safety analysis
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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)
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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
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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 Acetylsalicylic 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 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

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 title	Statistical analysis 3
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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

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 Acetylsalicyclic 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 Acetylsalicylic 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 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 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 Acetylsalicylic 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 Acetylsalicylic 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 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 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 Acetylsalicylic 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 Acetylsalicylic 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 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 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 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 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 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 44: 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 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 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 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
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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
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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 Acetylsalicylic 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 Acetylsalicylic 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 Acetylsalicylic 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 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	= 0.64
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 Acetylsalicylic 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 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 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 Acetylsalicylic 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 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	= 0.51
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 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	Cochran-Mantel-Haenszel

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	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 Acetylsalicylic 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 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	= 0.878
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 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	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 35: 2 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 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 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 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 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 44: 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 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 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 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 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
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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
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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 Acetylsalicylic 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 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 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 Acetylsalicylic 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 Acetylsalicylic 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 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 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 Acetylsalicylic 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 Acetylsalicylic 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 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 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 Acetylsalicylic 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 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 38: 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	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 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 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 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 47: 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	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
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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
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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 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: 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 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: TOTPAR 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: 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 Acetylsalicylic 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 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 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 Acetylsalicylic 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
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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
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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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	14.0
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Reporting groups

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

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