Clinical trial results:
A Multicenter, Double-Blind, Randomized, Parallel, Placebo-Controlled Trial Assessing the Analgesic Efficacy of a Single, Oral Dose of a Fast Release Aspirin 1000 mg in Postsurgical Dental Pain

Summary

EudraCT number	2014-005271-81
Trial protocol	Outside EU/EEA
Global end of trial date	07 July 2010

Results information

Result version number	v1
This version publication date	12 July 2016
First version publication date	19 July 2015

Trial information

Trial identification

Sponsor protocol code	BAY1019036/15120

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01117636
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	Therapeutic Area Head, Bayer HealthCare AG, clinical-trials-contact@bayerhealthcare.com
Scientific contact	Therapeutic Area Head, 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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	07 July 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 July 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the analgesic efficacy of a single, oral dose of fast release aspirin tablets, 1000 milligram (mg) (2 × 500 mg) compared to regular aspirin tablets, 1000 mg (2 × 500 mg) and placebo in subjects with postsurgical dental pain.

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and the International Conference on Harmonization guideline E6: Good Clinical Practice. 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	28 April 2010
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: 514
Worldwide total number of subjects	514
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)	51

Adults (18-64 years)	463
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study conducted at 2 study centers in the United States, from 03 May 2010 (first subject's first visit) to 06 July 2010 (last subject's last visit).

Pre-assignment

Screening details:

A total of 514 subjects enrolled in the study and were randomly assigned to 1 of 3 treatment groups.

Period 1

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

Arms

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

Arm description:

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

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

Dosage and administration details:

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

Arm title	Acetylsalicylic acid (Aspirin, BAY-E4465)

Arm description:

Single oral dose of regular aspirin tablet 1000 mg (2 x 500 mg) with a full glass of water (240 mL) between 1-4 hours post dental surgery.

Arm type	Experimental
Investigational medicinal product name	Acetylsalicyclic acid (Aspirin)
Investigational medicinal product code	BAY-E4465
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Single oral dose of regular aspirin tablet 1000 mg (2 x 500 mg) with a full glass of water (240 mL) between 1-4 hours post dental surgery.

Arm title	Placebo

Arm description:

Single oral dose of 2 placebo tablets 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 2 placebo tablets 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)	Acetylsalicylic acid (Aspirin, BAY-E4465)	Placebo
Started	206	203	105
Completed	206	203	105

Baseline characteristics

Reporting groups	
Reporting group title	Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Reporting group description:	
Single oral dose of fast release aspirin tablets 1000 mg (2 x 500 mg) with a full glass of water (240 milliliter [mL]) between 1-4 hours post dental surgery.	
Reporting group title	Acetylsalicylic acid (Aspirin, BAY-E4465)
Reporting group description:	
Single oral dose of regular aspirin tablet 1000 mg (2 x 500 mg) with a full glass of water (240 mL) between 1-4 hours post dental surgery.	
Reporting group title	Placebo
Reporting group description:	
Single oral dose of 2 placebo tablets with a full glass of water (240 mL) between 1-4 hours post dental surgery.	

Reporting group values	Acetylsalicylic acid (Fast release Aspirin, BAY1019036)	Acetylsalicylic acid (Aspirin, BAY-E4465)	Placebo
Number of subjects	206	203	105
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	22.4	22.7	22.5
standard deviation	± 4.62	± 4.85	± 4.24
Gender categorical Units: Subjects			
Female	114	118	52
Male	92	85	53
Categorical Pain Intensity Units: Subjects			
No Pain	0	0	0
Mild Pain	0	0	0
Moderate Pain	166	163	83
Severe Pain	40	40	22
11-point Pain Intensity Units: scores on a scale			
arithmetic mean	6.6	6.5	6.6
standard deviation	± 1.14	± 1.07	± 1.17

Reporting group values	Total		
Number of subjects	514		
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	- -		
Gender categorical Units: Subjects			
Female	284		
Male	230		
Categorical Pain Intensity Units: Subjects			
No Pain	0		
Mild Pain	0		
Moderate Pain	412		
Severe Pain	102		
11-point Pain Intensity Units: scores on a scale arithmetic mean standard deviation	 -		

End points

End points reporting groups

Reporting group title	Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Reporting group description:	
Single oral dose of fast release aspirin tablets 1000 mg (2 x 500 mg) with a full glass of water (240 milliliter [mL]) between 1-4 hours post dental surgery.	
Reporting group title	Acetylsalicylic acid (Aspirin, BAY-E4465)
Reporting group description:	
Single oral dose of regular aspirin tablet 1000 mg (2 x 500 mg) with a full glass of water (240 mL) between 1-4 hours post dental surgery.	
Reporting group title	Placebo
Reporting group description:	
Single oral dose of 2 placebo tablets with a full glass of water (240 mL) between 1-4 hours post dental surgery.	
Subject analysis set title	Intent-to-treat (ITT)
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Subjects who took at least 1 dose of the study drug and who had at least 1 postdose assessment on an efficacy parameter.	

Primary: Time to First Perceptible Pain Relief (PR)

End point title	Time to First Perceptible Pain Relief (PR)
End point description:	
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, and the first stopwatch was stopped; if a subject recorded a score of a little relief (1) or greater on the pain relief rating scale or had a pain intensity difference (PID) score of at least 1 at an analysis time point preceding the time the stopwatch was stopped, then that analysis time point was considered the "Time to first perceptible PR".	
End point type	Primary
End point timeframe:	
0 to 6 hours	

End point values	Acetylsalicylic acid (Fast release Aspirin, BAY1019036)	Acetylsalicylic acid (Aspirin, BAY-E4465)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	206[1]	203[2]	105[3]	
Units: minutes				
median (confidence interval 95%)	16.3 (12.18 to 19.22)	20 (15.68 to 23.4)	20 (18.95 to 30)	

Notes:

[1] - ITT population

[2] - ITT population

[3] - ITT population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)

Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Logrank

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logrank

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.014
Method	Logrank

Primary: Time to First Perceptible Pain Relief (PR) Confirmed

End point title	Time to First Perceptible Pain Relief (PR) Confirmed

End point description:

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 PID score of at least 1 at the next time point assessment.

End point type	Primary

End point timeframe:

0 to 6 hours

End point values	Acetylsalicylic acid (Fast release Aspirin, BAY1019036)	Acetylsalicylic acid (Aspirin, BAY-E4465)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	206[4]	203[5]	105[6]	
Units: minutes				
median (confidence interval 95%)	18.9 (16.62 to 19.85)	24 (19.85 to 29.42)	22.8 (20 to 45.55)	

Notes:

[4] - ITT population

[5] - ITT population

[6] - ITT population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Logrank

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logrank

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.011
Method	Logrank

Secondary: Time to Meaningful Pain Relief (PR)

End point title	Time to Meaningful Pain Relief (PR)

End point description:

Time to meaningful PR was defined as the duration from subject taking the study drug until the second stopwatch was stopped, provided that the subject experienced both "perceptible" and "meaningful" PR. Subjects who did not achieve meaningful PR after 6 hours after dosing were censored at the 6-hour postdose time point; subjects who took rescue medication before experiencing meaningful PR were censored at the 6-hour postdose time point. '99999' in the below table indicates data was not analysed as upper limit of 95% confidence interval was not reached.

End point type	Secondary

End point timeframe: 0 to 6 hours

End point values	Acetylsalicylic acid (Fast release Aspirin, BAY1019036)	Acetylsalicylic acid (Aspirin, BAY-E4465)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	206[7]	203[8]	105[9]	
Units: minutes				
median (confidence interval 95%)	49.4 (40.22 to 57.68)	99.2 (76.98 to 148.35)	99999 (99999 to 99999)	

Notes:

[7] - ITT population

[8] - ITT population

[9] - ITT population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.038
Method	Logrank

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logrank

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logrank

Secondary: Pain Intensity at 10, 20, 30, 40, 50, and 60 Minutes and at 2, 3, 4, 5, and 6 Hours After Dosing

End point title	Pain Intensity at 10, 20, 30, 40, 50, and 60 Minutes and at 2, 3, 4, 5, and 6 Hours After Dosing

End point description:

Pain Intensity (PI) was rated by subjects on a 4-point Categorical Pain Intensity 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:

10, 20, 30, 40, and 50 minutes and at 1, 2, 3, 4, 5, and 6 hours post-dose

End point values	Acetylsalicylic acid (Fast release Aspirin, BAY1019036)	Acetylsalicylic acid (Aspirin, BAY-E4465)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	206[10]	203[11]	105[12]	
Units: Subjects				
10 minutes: No Pain	2	2	0	
10 minutes: Mild Pain	22	21	10	
10 minutes: Moderate Pain	132	123	65	
10 minutes: Severe Pain	50	57	30	
20 minutes: No Pain	8	3	2	
20 minutes: Mild Pain	59	36	18	
20 minutes: Moderate Pain	105	113	56	
20 minutes: Severe Pain	34	51	29	
30 minutes: No Pain	21	8	3	
30 minutes: Mild Pain	90	49	20	
30 minutes: Moderate Pain	73	103	47	
30 minutes: Severe Pain	22	43	35	
40 minutes: No Pain	31	12	3	
40 minutes: Mild Pain	101	64	23	
40 minutes: Moderate Pain	55	89	42	
40 minutes: Severe Pain	18	38	37	
50 minutes: No Pain	40	21	4	
50 minutes: Mild Pain	96	68	24	
50 minutes: Moderate Pain	53	81	43	
50 minutes: Severe Pain	17	33	34	
1 hour: No Pain	44	23	6	
1 hour: Mild Pain	99	75	24	
1 hour: Moderate Pain	43	67	37	
1 hour: Severe Pain	20	38	38	
2 hours: No Pain	31	28	4	
2 hours: Mild Pain	64	70	24	
2 hours: Moderate Pain	60	52	26	
2 hours: Severe Pain	51	53	51	
3 hours: No Pain	19	27	10	

3 hours: Mild Pain	59	64	19	
3 hours: Moderate Pain	56	48	20	
3 hours: Severe Pain	72	64	56	
4 hours: No Pain	15	26	12	
4 hours: Mild Pain	49	57	17	
4 hours: Moderate Pain	64	47	20	
4 hours: Severe Pain	78	73	56	
5 hours: No Pain	12	27	12	
5 hours: Mild Pain	50	56	19	
5 hours: Moderate Pain	63	42	18	
5 hours: Severe Pain	81	78	56	
6 hours: No Pain	9	22	13	
6 hours: Mild Pain	47	48	16	
6 hours: Moderate Pain	66	53	20	
6 hours: Severe Pain	84	80	56	

Notes:

[10] - ITT population

[11] - ITT population

[12] - ITT population

Statistical analyses

Statistical analysis title	Statistical analysis 1: 10 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.464
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 2: 10 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.352
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 3: 10 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)

Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.761
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 4: 20 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 5: 20 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 6: 20 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.743
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 7: 30 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 8: 30 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 9: 30 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.034
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 10: 40 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 11: 40 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 12: 40 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)

Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 13: 50 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 14: 50 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 15: 50 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 16: 1 hour post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 17: 1 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 18: 1 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 19: 2 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.999
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 20: 2 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 21: 2 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)

Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 22: 3 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.168
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 23: 3 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.01
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 24: 3 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 25: 4 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.123
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 26: 4 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.085
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 27: 4 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 28: 5 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.106
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 29: 5 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.197
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 30: 5 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)

Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.022
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 31: 6 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.212
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 32: 6 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.301
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 33: 6 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.067
Method	Cochran-Mantel-Haenszel

Secondary: Pain Intensity Difference (PID) at 10, 20, 30, 40, 50, and 60 Minutes and at 2, 3, 4, 5, and 6 Hours After Dosing

End point title	Pain Intensity Difference (PID) at 10, 20, 30, 40, 50, and 60 Minutes and at 2, 3, 4, 5, and 6 Hours After Dosing

End point description:

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

End point type	Secondary

End point timeframe:
10, 20, 30, 40, 50, and 60 minutes and at 2, 3, 4, 5, and 6 hours post-dose

End point values	Acetylsalicylic acid (Fast release Aspirin, BAY1019036)	Acetylsalicylic acid (Aspirin, BAY-E4465)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	206[13]	203[14]	105[15]	
Units: scores on a scale				
arithmetic mean (standard deviation)				
10 Minutes post-dose	0.1 (± 0.52)	0.1 (± 0.56)	0 (± 0.47)	
20 Minutes post-dose	0.4 (± 0.71)	0.2 (± 0.62)	0.2 (± 0.65)	
30 Minutes post-dose	0.8 (± 0.82)	0.4 (± 0.72)	0.1 (± 0.73)	
40 Minutes post-dose	1 (± 0.87)	0.5 (± 0.79)	0.1 (± 0.78)	
50 Minutes post-dose	1 (± 0.89)	0.6 (± 0.86)	0.2 (± 0.79)	
1 Hour post-dose	1 (± 0.91)	0.7 (± 0.91)	0.2 (± 0.84)	
2 Hours post-dose	0.6 (± 1.02)	0.6 (± 1.01)	0 (± 0.87)	
3 Hours post-dose	0.4 (± 1.01)	0.5 (± 1.06)	0.1 (± 1.03)	
4 Hours post-dose	0.2 (± 0.98)	0.4 (± 1.06)	0.1 (± 1.04)	
5 Hours post-dose	0.2 (± 0.94)	0.4 (± 1.08)	0.1 (± 1.04)	
6 Hours post-dose	0.1 (± 0.9)	0.3 (± 1.03)	0.1 (± 1.05)	

Notes:
[13] - ITT population
[14] - ITT population
[15] - ITT population

Statistical analyses

Statistical analysis title	Statistical analysis 1: 10 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.604
Method	ANCOVA

Statistical analysis title	Statistical analysis 2: 10 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.148
Method	ANCOVA

Statistical analysis title	Statistical analysis 3: 10 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.31
Method	ANCOVA

Statistical analysis title	Statistical analysis 4: 20 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 5: 20 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 6: 20 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.525
Method	ANCOVA

Statistical analysis title	Statistical analysis 7: 30 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)

Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 8: 30 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 9: 30 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.015
Method	ANCOVA

Statistical analysis title	Statistical analysis 10: 40 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 11: 40 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 12: 40 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 13: 50 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 14: 50 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 15: 50 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 16: 1 hour post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)

Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 17: 1 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 18: 1 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 19: 2 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.938
Method	ANCOVA

Statistical analysis title	Statistical analysis 20: 2 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 21: 2 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 22: 3 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.118
Method	ANCOVA

Statistical analysis title	Statistical analysis 23: 3 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.016
Method	ANCOVA

Statistical analysis title	Statistical analysis 24: 3 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 25: 4 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)

Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.064
Method	ANCOVA

Statistical analysis title	Statistical analysis 26: 4 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.194
Method	ANCOVA

Statistical analysis title	Statistical analysis 27: 4 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.005
Method	ANCOVA

Statistical analysis title	Statistical analysis 28: 5 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.039
Method	ANCOVA

Statistical analysis title	Statistical analysis 29: 5 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.404
Method	ANCOVA

Statistical analysis title	Statistical analysis 30: 5 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.011
Method	ANCOVA

Statistical analysis title	Statistical analysis 31: 6 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.089
Method	ANCOVA

Statistical analysis title	Statistical analysis 32: 6 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.66
Method	ANCOVA

Statistical analysis title	Statistical analysis 33: 6 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.066
Method	ANCOVA

Secondary: Pain Relief at 10, 20, 30, 40, 50, and 60 Minutes and at 2, 3, 4, 5, and 6 Hours After Dosing

End point title	Pain Relief at 10, 20, 30, 40, 50, and 60 Minutes and at 2, 3, 4, 5, and 6 Hours After Dosing

End point description:

Pain relief was rated by subjects using a 5-point Categorical Relief Rating Scale (0 = no relief, 1 = a little relief, 2 = some relief, 3 = a lot of relief, 4 = complete relief).

End point type	Secondary

End point timeframe:

10, 20, 30, 40, 50, and 60 minutes and at 2, 3, 4, 5, and 6 hours post-dose

End point values	Acetylsalicylic acid (Fast release Aspirin, BAY1019036)	Acetylsalicylic acid (Aspirin, BAY-E4465)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	206[16]	203[17]	105[18]	
Units: Subjects				
10 minutes: No relief	128	129	72	
10 minutes: Little relief	57	50	22	
10 minutes: Some relief	14	20	8	
10 minutes: Lot of relief	5	2	3	
10 minutes: Complete relief	2	2	0	
20 minutes: No relief	70	104	54	
20 minutes: Little relief	74	62	31	
20 minutes: Some relief	40	26	14	
20 minutes: Lot of relief	14	8	4	
20 minutes: Complete relief	8	3	2	
30 minutes: No relief	42	84	50	
30 minutes: Little relief	55	54	30	
30 minutes: Some relief	61	40	17	
30 minutes: Lot of relief	28	17	5	
30 minutes: Complete relief	20	8	3	
40 minutes: No relief	27	71	51	
40 minutes: Little relief	48	50	24	
40 minutes: Some relief	47	42	18	
40 minutes: Lot of relief	54	29	9	
40 minutes: Complete relief	30	11	3	
50 minutes: No relief	23	55	49	
50 minutes: Little relief	40	51	24	
50 minutes: Some relief	47	46	19	
50 minutes: Lot of relief	56	32	9	
50 minutes: Complete relief	40	19	4	
1 hour: No relief	28	57	52	
1 hour: Little relief	35	44	21	
1 hour: Some relief	38	43	15	
1 hour: Lot of relief	62	38	13	
1 hour: Complete relief	43	21	4	
2 hours: No relief	70	74	62	
2 hours: Little relief	34	23	15	
2 hours: Some relief	33	37	12	
2 hours: Lot of relief	39	42	12	
2 hours: Complete relief	30	27	4	
3 hours: No relief	97	86	70	

3 hours: Little relief	25	27	6	
3 hours: Some relief	35	23	10	
3 hours: Lot of relief	32	41	8	
3 hours: Complete relief	17	26	11	
4 hours: No relief	107	99	73	
4 hours: Little relief	21	21	3	
4 hours: Some relief	33	23	4	
4 hours: Lot of relief	31	35	13	
4 hours: Complete relief	14	25	12	
5 hours: No relief	121	105	73	
5 hours: Little relief	21	16	0	
5 hours: Some relief	28	25	6	
5 hours: Lot of relief	24	30	14	
5 hours: Complete relief	12	27	12	
6 hours: No relief	127	114	73	
6 hours: Little relief	16	20	0	
6 hours: Some relief	25	17	5	
6 hours: Lot of relief	29	30	13	
6 hours: Complete relief	9	22	14	

Notes:

[16] - ITT population

[17] - ITT population

[18] - ITT population

Statistical analyses

Statistical analysis title	Statistical analysis 1: 10 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.864
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 2: 10 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.326
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 3: 10 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)

Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.41
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 4: 20 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 5: 20 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.002
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 6: 20 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.966
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 7: 30 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 8: 30 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 9: 30 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.148
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 10: 40 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 11: 40 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 12: 40 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)

Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.011
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 13: 50 minutes post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 14: 50 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 15: 50 minutes post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 16: 1 hour post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 17: 1 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 18: 1 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 19: 2 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.911
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 20: 2 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 21: 2 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)

Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 22: 3 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.144
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 23: 3 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.008
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 24: 3 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 25: 4 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.231
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 26: 4 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.053
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 27: 4 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.007
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 28: 5 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.034
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 29: 5 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.429
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 30: 5 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)

Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.024
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 31: 6 hours post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.137
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 32: 6 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.745
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 33: 6 hours post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.149
Method	Cochran-Mantel-Haenszel

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 to 6 hours post-dose	

End point values	Acetylsalicylic acid (Fast release Aspirin, BAY1019036)	Acetylsalicylic acid (Aspirin, BAY-E4465)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	206[19]	203[20]	105[21]	
Units: scores on a scale				
arithmetic mean (standard deviation)				
SPID 0 – 2	1.3 (± 1.53)	1 (± 1.48)	0.2 (± 1.35)	
SPID 0 – 4	1.9 (± 3.16)	2 (± 3.38)	0.3 (± 3.2)	
SPID 0 – 6	2.3 (± 4.72)	2.8 (± 5.28)	0.5 (± 5.18)	

Notes:

[19] - ITT population

[20] - ITT population

[21] - ITT population

Statistical analyses

Statistical analysis title	Statistical analysis 1: SPID 0-2
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.026
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	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 3: SPID 0-2
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)

Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 4: SPID 0-4
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.922
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	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 6: SPID 0-4
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 7: SPID 0-6
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.403
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	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.003
Method	ANCOVA

Statistical analysis title	Statistical analysis 9: SPID 0-6
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

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

End point title	Summed Total Pain Relief (TOTPAR) From Hour 0 Through Hour 2, Hour 4 and Hour 6

End point description:

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

End point type	Secondary

End point timeframe:

0-6 hours post-dose

End point values	Acetylsalicylic acid (Fast release Aspirin, BAY1019036)	Acetylsalicylic acid (Aspirin, BAY-E4465)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	206[22]	203[23]	105[24]	
Units: scores on a scale				
arithmetic mean (standard deviation)				
TOTPAR 0 – 2	3.3 (± 2.22)	2.8 (± 2.21)	1.7 (± 1.98)	
TOTPAR 0 – 4	5.7 (± 4.46)	5.6 (± 4.84)	3.5 (± 4.64)	
TOTPAR 0 – 6	7.6 (± 6.56)	8 (± 7.5)	5.5 (± 7.57)	

Notes:
[22] - ITT population
[23] - ITT population
[24] - ITT population

Statistical analyses

Statistical analysis title	Statistical analysis 1: TOTPAR 0-2
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.018
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	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 3: TOTPAR 0-2
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 4: TOTPAR 0-4
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.882
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	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 6: TOTPAR 0-4
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA

Statistical analysis title	Statistical analysis 7: TOTPAR 0-6
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.463
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	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.013
Method	ANCOVA

Statistical analysis title	Statistical analysis 9: TOTPAR 0-6
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)

Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.002
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 defined as the duration from when the subject took the study drug until the time of the first use of rescue medication. Subjects who did not take any rescue medication were censored at the 6-hour post-dose time point. '99999' in the below table indicates data was not analysed as upper limit of 95% confidence interval was not reached.

End point type	Secondary

End point timeframe:

0 to 6 hours

End point values	Acetylsalicylic acid (Fast release Aspirin, BAY1019036)	Acetylsalicylic acid (Aspirin, BAY-E4465)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	206[25]	203[26]	105[27]	
Units: hours				
median (confidence interval 95%)	251.5 (199 to 325)	99999 (245 to 99999)	124 (95 to 152)	

Notes:

[25] - ITT population

[26] - ITT population

[27] - ITT population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.225
Method	Logrank

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)

Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Logrank

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
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 and Fischer exact 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)	Acetylsalicylic acid (Aspirin, BAY-E4465)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	206[28]	203[29]	105[30]	
Units: percentage of subjects				
number (not applicable)				
1 hour post-dose	1	0	2.9	
2 hour post-dose	18.4	19.7	47.6	
3 hour post-dose	36.4	34	61.9	
4 hour post-dose	47.1	41.4	67.6	
5 hour post-dose	52.9	47.3	67.6	
6 hour post-dose	57.8	49.8	68.6	

Notes:

[28] - ITT population

[29] - ITT population

[30] - ITT population

Statistical analyses

Statistical analysis title	Statistical analysis 1: 1 hour post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.499
Method	Fisher exact

Statistical analysis title	Statistical analysis 2: 1 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.34
Method	Fisher exact

Statistical analysis title	Statistical analysis 3: 1 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.039
Method	Fisher exact

Statistical analysis title	Statistical analysis 4: 2 hour post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.746
Method	Chi-squared

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

Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Chi-squared

Statistical analysis title	Statistical analysis 6: 2 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Chi-squared

Statistical analysis title	Statistical analysis 7: 3 hour post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.609
Method	Chi-squared

Statistical analysis title	Statistical analysis 8: 3 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Chi-squared

Statistical analysis title	Statistical analysis 9: 3 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Chi-squared

Statistical analysis title	Statistical analysis 10: 4 hour post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.245
Method	Chi-squared

Statistical analysis title	Statistical analysis 11: 4 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Chi-squared

Statistical analysis title	Statistical analysis 12: 4 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Chi-squared

Statistical analysis title	Statistical analysis 13: 5 hour post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.256
Method	Chi-squared

Statistical analysis title	Statistical analysis 14: 5 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)

Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.013
Method	Chi-squared

Statistical analysis title	Statistical analysis 15: 5 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Chi-squared

Statistical analysis title	Statistical analysis 16: 6 hour post-dose
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.104
Method	Chi-squared

Statistical analysis title	Statistical analysis 17: 6 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.064
Method	Chi-squared

Statistical analysis title	Statistical analysis 18: 6 hour post-dose
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.002
Method	Chi-squared

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

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

End point description:

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

End point type	Secondary

End point timeframe:

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

End point values	Acetylsalicylic acid (Fast release Aspirin, BAY1019036)	Acetylsalicylic acid (Aspirin, BAY-E4465)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	206[31]	203[32]	105[33]	
Units: subjects				
Poor	53	64	61	
Fair	54	42	14	
Good	46	57	20	
Very Good	37	28	6	
Excellent	13	11	3	

Notes:

[31] - ITT population

[32] - ITT population

[33] - ITT population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Acetylsalicylic acid (Aspirin, BAY-E4465) v Acetylsalicylic acid (Fast release Aspirin, BAY1019036)
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.348
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	311
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v Acetylsalicylic acid (Aspirin, BAY-E4465)
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	other
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.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	12.1

Reporting groups

Reporting group title	Placebo

Reporting group description:

Single oral dose of 2 placebo tablets with a full glass of water (240 mL) between 1-4 hours post dentalsurgery.

Reporting group title	Fast Release Aspirin

Reporting group description:

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

Reporting group title	Regular Aspirin

Reporting group description:

Single oral dose of regular aspirin tablet 1000 mg (2 x 500 mg) with a full glass of water (240 mL)between 1-4 hours post dental surgery.

Serious adverse events	Placebo	Fast Release Aspirin	Regular Aspirin
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 105 (0.00%)	0 / 206 (0.00%)	0 / 203 (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	Placebo	Fast Release Aspirin	Regular Aspirin
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 105 (21.90%)	38 / 206 (18.45%)	31 / 203 (15.27%)
Injury, poisoning and procedural complications			
Operative haemorrhage			
subjects affected / exposed	1 / 105 (0.95%)	0 / 206 (0.00%)	0 / 203 (0.00%)
occurrences (all)	1	0	0
Periorbital haematoma			

subjects affected / exposed	0 / 105 (0.00%)	1 / 206 (0.49%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Post procedural haematoma			
subjects affected / exposed	0 / 105 (0.00%)	1 / 206 (0.49%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Burning sensation			
subjects affected / exposed	1 / 105 (0.95%)	0 / 206 (0.00%)	0 / 203 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	2 / 105 (1.90%)	4 / 206 (1.94%)	2 / 203 (0.99%)
occurrences (all)	2	5	2
Headache			
subjects affected / exposed	9 / 105 (8.57%)	8 / 206 (3.88%)	14 / 203 (6.90%)
occurrences (all)	9	8	14
Paraesthesia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 206 (0.00%)	0 / 203 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	0 / 105 (0.00%)	1 / 206 (0.49%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	1 / 105 (0.95%)	0 / 206 (0.00%)	0 / 203 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	1 / 105 (0.95%)	0 / 206 (0.00%)	0 / 203 (0.00%)
occurrences (all)	1	0	0
Feeling hot			
subjects affected / exposed	0 / 105 (0.00%)	2 / 206 (0.97%)	0 / 203 (0.00%)
occurrences (all)	0	2	0
Pain			
subjects affected / exposed	0 / 105 (0.00%)	0 / 206 (0.00%)	1 / 203 (0.49%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			

Ear pain			
subjects affected / exposed	2 / 105 (1.90%)	0 / 206 (0.00%)	0 / 203 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 105 (0.00%)	1 / 206 (0.49%)	1 / 203 (0.49%)
occurrences (all)	0	1	1
Abdominal pain upper			
subjects affected / exposed	1 / 105 (0.95%)	0 / 206 (0.00%)	0 / 203 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 105 (0.00%)	1 / 206 (0.49%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 206 (0.00%)	0 / 203 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	5 / 105 (4.76%)	8 / 206 (3.88%)	6 / 203 (2.96%)
occurrences (all)	5	8	7
Vomiting			
subjects affected / exposed	3 / 105 (2.86%)	5 / 206 (2.43%)	1 / 203 (0.49%)
occurrences (all)	3	5	1
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 206 (0.49%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 105 (0.00%)	1 / 206 (0.49%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Dental alveolar anomaly			
subjects affected / exposed	1 / 105 (0.95%)	0 / 206 (0.00%)	0 / 203 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 206 (0.00%)	0 / 203 (0.00%)
occurrences (all)	2	0	0

Infections and infestations			
Alveolar osteitis			
subjects affected / exposed	5 / 105 (4.76%)	12 / 206 (5.83%)	9 / 203 (4.43%)
occurrences (all)	5	13	10
Nasopharyngitis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 206 (0.49%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 105 (0.00%)	1 / 206 (0.49%)	0 / 203 (0.00%)
occurrences (all)	0	1	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 April 2010	Amendment 1 added physical examination and urine drug screen assessments, which were inadvertently omitted from the original protocol, to the protocol text.

Notes:

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 were not calculated.

Notes: