Clinical trial results:
Clinical pilot study to review the impact of perioperative administration of the synthetic cannabinoid nabilone in the context of spinal fusion surgery on the coping with surgery and the pain perception of patients with severely reduced quality of life

Summary

EudraCT number	2015-004227-31
Trial protocol	AT
Global end of trial date	20 February 2020

Results information

Result version number	v1 (current)
This version publication date	19 November 2021
First version publication date	19 November 2021

Trial information

Trial identification

Sponsor protocol code	1312/BP

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Abteilung für Wirbelsäulenchirurgie, Orthopädisches Spital Speising GmbH
Sponsor organisation address	Speisinger Strasse 109, Vienna, Austria, 1130
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Scientific contact	Dr. Astrid Pinsger-Plank, OA Dr. Philipp Becker c/o Abteilung für Wirbelsäulenchirurgie, Orthopädisches Spital Speising GmbH, 00431 801821183, philipp.becker@oss.at

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	15 April 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 February 2020
Global end of trial reached?	Yes
Global end of trial date	20 February 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to gain first insights into the effects of pre-, peri- and postoperative cannabinoid intake on the physical and psychological coping with surgery as well as on the pain perception of patients with severely reduced quality of life.

Protection of trial subjects:

Throughout the study all involved investigators adhered to the law as laid down in the European Regulation (EU) 2016/679 as well as to the national data protection law. Safety Assessments Tolerability was described through the: number of subjects (%) who discontinue the study and the number of subjects (%) who discontinue the study due to AE safety measures included the following: AEs, SAEs, SUSARs, clinical and laboratory assessment, vital parameters (oxygenation, heart rate and blood pressure during surgery), patients' compliance and medication use (prior for relevant medication, concomitant).

Background therapy:

All subjects enrolled in the study underwent elective spinal fusion surgery in 1-2 segments for spinal degeneration.

Evidence for comparator:

Use of placebo to realize a double-blind design

Actual start date of recruitment	25 February 2016
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	Austria: 36
Worldwide total number of subjects	36
EEA total number of subjects	36

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	13
From 65 to 84 years	22
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Study participants were recruited among the patients planned for spinal fusion surgery (one to max. two segments) at the orthopedic hospital Speising. To avoid falsification of population representation and by ethical concerns, there was not any pre-selection performed (e.g. by social status, etc.) before checking inclusion criteria.

Pre-assignment

Screening details:

Screening Criteria:
- elective spinale fusion surgery (1-2 segments)
- >18 years

Approx. 500 people screened

Reasons for excluding:
- Participation in another trial
- Expected drop out due to hospital-hometown-distance

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, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

Random allocation
Stratified randomization

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo (K-Gruppe)

Arm description:

12 participants, no active ingredient

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

Dosage and administration details:

For placebo capsules, 147.1 mg corn starch are filled into hard gelatine capsules of the same type and size, manufactured by AOP Orphan Pharmaceuticals AG (Vienna, Austria).

The capsules were taken as followed:
Pre-OP-phase (day 0-2 days pre-OP): 1 capsule at approx. 8 p.m. daily, 0,0mg Nabilone daily
Peri-OP-Phase (1 day pre-OP-day 4 post-OP): 2 capsules at approx. 8 p.m. daily, 0,0mg Nabilone daily
Post-OP-phase (day 5 post-OP-35-49 days post-OP): ad libitum, 0, 1 or 2 capsules at approx. 8 p.m. daily, 0,0mg Nabilone daily

Arm title	Nabilone (V-Gruppe)

Arm description:

In this group all 24 participants take capsules that contain the active ingredient Nabilone, manufactured

by AOP Orphan Pharmaceuticals AG (Vienna, Austria).

Arm type	Experimental
Investigational medicinal product name	Nabilone 0,25mg capsules
Investigational medicinal product code	1-31358
Other name	Canemes
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Canemes 1 mg capsules consist of the following compounds (manufactured by AOP Orphan Pharmaceuticals AG (Vienna, Austria)):
- Nabilone
- Povidone, (Kollidon 25), K25
- Corn starch, Starch 1500
- Ethanol (not present in the product)

The capsules were taken as followed:
Pre-OP-phase (day 0-2 days pre-OP): 1 capsule at approx. 8 p.m. daily --> 0,25mg Nabilone daily
Peri-OP-Phase (1 day pre-OP-day 4 post-OP): 2 capsules at approx. 8 p.m. daily --> 0,5mg Nabilone daily
Post-OP-phase (day 5 post-OP-35-49 days post-OP): ad libitum, 0, 1 or 2 capsules at approx. 8 p.m. daily --> 0,0mg, 0,25mg or 0,5mg Nabilone daily

Number of subjects in period 1	Placebo (K-Gruppe)	Nabilone (V-Gruppe)
Started	12	24
Completed	11	15
Not completed	1	9
Adverse event, non-fatal	1	7
Lack of efficacy	-	1
Protocol deviation	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo (K-Gruppe)
Reporting group description:	
12 participants, no active ingredient	

Reporting group title	Nabilone (V-Gruppe)
Reporting group description:	
In this group all 24 participants take capsules that contain the active ingredient Nabilone, manufactured by AOP Orphan Pharmaceuticals AG (Vienna, Austria).	

Reporting group values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	Total
Number of subjects	12	24	36
Age categorical			
Age was measured at baseline (U1)			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	9	14
From 65-84 years	6	15	21
85 years and over	1	0	1
Age continuous			
Units: years			
median	74	73	
inter-quartile range (Q1-Q3)	61.5 to 77.5	53 to 76.5	-
Gender categorical			
Units: Subjects			
Female	8	12	20
Male	4	12	16

Subject analysis sets	
Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
ITT = Intent to Treat	
Subject analysis set title	PP
Subject analysis set type	Per protocol
Subject analysis set description:	
PP = Per Protocol	

Reporting group values	ITT	PP	
Number of subjects	36	24	
Age categorical			
Age was measured at baseline (U1)			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	14	10	
From 65-84 years	21	16	
85 years and over	1	0	
Age continuous			
Units: years			
median			
inter-quartile range (Q1-Q3)			
Gender categorical			
Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	Placebo (K-Gruppe)
Reporting group description:	
12 participants, no active ingredient	

Reporting group title	Nabilone (V-Gruppe)
Reporting group description:	
In this group all 24 participants take capsules that contain the active ingredient Nabilone, manufactured by AOP Orphan Pharmaceuticals AG (Vienna, Austria).	

Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
ITT = Intent to Treat	
Subject analysis set title	PP
Subject analysis set type	Per protocol
Subject analysis set description:	
PP = Per Protocol	

Primary: Change in HADS anxiety U1 to U2 [-] ITT

End point title	Change in HADS anxiety U1 to U2 [-] ITT
End point description:	
U1 -- Baseline U2 -- 1 day preop	
End point type	Primary
End point timeframe:	
U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	23	34	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-1.00 (-2.00 to 1.00)	0.00 (-1.00 to 4.00)	0.00 (-1.00 to 4.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Nabilone (V-Gruppe) v Placebo (K-Gruppe)

Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.537 [1]
Method	Wilcoxon (Mann-Whitney)

Notes:

[1] - purely dcescriptive

Primary: Change in HADS anxiety U1 to U7 [-] ITT

End point title	Change in HADS anxiety U1 to U7 [-] ITT
End point description:	
U1 -- Baseline U7 -- 42 days postop	
End point type	Primary
End point timeframe:	
U1-U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	16	27	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-3.00 (-5.00 to -1.00)	-2.00 (-6.00 to 0.00)	-3.00 (-6.00 to 0.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Nabilone (V-Gruppe) v Placebo (K-Gruppe)
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.971 [2]
Method	Wilcoxon (Mann-Whitney)

Notes:

[2] - purely descriptive

Primary: Change in HADS anxiety U1 to U8 [-] ITT

End point title	Change in HADS anxiety U1 to U8 [-] ITT
End point description:	
U1 -- Baseline U8 -- 84 days postop	
End point type	Primary
End point timeframe:	
U1-U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	14	24	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-1.00 (-3.00 to 2.00)	-1.00 (-5.00 to 0.00)	-1.00 (-3.00 to 0.50)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.388 [3]
Method	Wilcoxon (Mann-Whitney)

Notes:

[3] - purely descriptive

Primary: Change in HADS depression U1 to U2 [-] ITT

End point title	Change in HADS depression U1 to U2 [-] ITT
End point description:	
U1 -- Baseline U2 -- 1 day preop	
End point type	Primary
End point timeframe:	
U1-U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	23	34	
Units: [-]				
median (inter-quartile range (Q1-Q3))	0.00 (-1.00 to 3.00)	0.00 (-1.00 to 5.00)	0.00 (-1.00 to 3.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.383 [4]
Method	Wilcoxon (Mann-Whitney)

Notes:

[4] - purely descriptive

Primary: Change in HADS depression U1 to U7 [-] ITT

End point title	Change in HADS depression U1 to U7 [-] ITT
End point description:	
U1 -- Baseline U7 -- 42 days postop	
End point type	Primary
End point timeframe:	
U1-U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	16	27	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-1.00 (-5.00 to -1.00)	-1.00 (-3.00 to 0.00)	-1.00 (-4.00 to 0.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.547 [5]
Method	Wilcoxon (Mann-Whitney)

Notes:

[5] - purely descriptive

Primary: Change in HADS depression U1 to U8 [-] ITT

End point title	Change in HADS depression U1 to U8 [-] ITT
End point description:	
U1 -- Baseline U8 -- 84 days postop	
End point type	Primary
End point timeframe:	
U1-U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	14	24	
Units: [-]				
arithmetic mean (standard deviation)	-1.10 (± 2.64)	-1.64 (± 2.06)	-1.42 (± 2.28)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.577
Method	t-test, 2-sided

Primary: Change in Oswestry Low Back Pain Disability Questionaire U1 to U2 [%] ITT

End point title	Change in Oswestry Low Back Pain Disability Questionaire U1 to U2 [%] ITT
End point description: U1 -- Baseline U2 -- 1 day preop	
End point type	Primary
End point timeframe: U1-U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	23	34	
Units: [%]				
median (inter-quartile range (Q1-Q3))	-6.00 (-6.67 to -1.11)	-2.00 (-4.44 to 6.67)	-2.11 (-6.00 to 4.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.072 [6]
Method	Wilcoxon (Mann-Whitney)

Notes:

[6] - purely descriptive

Primary: Change in Oswestry Low Back Pain Disability Questionaire U1 to U7 [%] ITT

End point title	Change in Oswestry Low Back Pain Disability Questionaire U1 to U7 [%] ITT

End point description:

U1 -- Baseline
U7 -- 42 days postop

End point type	Primary

End point timeframe:

U1-U7

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	16	27	
Units: [%]				
arithmetic mean (standard deviation)	-16.00 (± 15.87)	-8.99 (± 15.90)	-11.84 (± 15.97)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.27 [7]
Method	t-test, 2-sided

Notes:

[7] - purely descriptive

Primary: Change in Oswestry Low Back Pain Disability Questionaire U1 to U8 [%] ITT

End point title	Change in Oswestry Low Back Pain Disability Questionaire U1 to U8 [%] ITT

End point description:

U1 -- Baseline

U8 -- 84 days postop

End point type	Primary

End point timeframe:

U1-U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	14	24	
Units: [%]				
arithmetic mean (standard deviation)	-20.26 (± 13.71)	-13.54 (± 12.31)	-16.34 (± 13.06)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.221 [8]
Method	t-test, 2-sided

Notes:

[8] - purely descriptive

Primary: Change in FABQ U1 to U2 [-] ITT

End point title	Change in FABQ U1 to U2 [-] ITT

End point description:

U1 -- Baseline
U2 -- 1 day preop

End point type	Primary

End point timeframe:

U1-U2

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	14	19	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-3.03 (-3.79 to -1.52)	0.00 (-6.06 to 6.06)	-1.52 (-6.06 to 0.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	19
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.348 [9]
Method	Wilcoxon (Mann-Whitney)

Notes:

[9] - purely descriptive

Primary: Change in FABQ U1 to U7 [-] ITT

End point title	Change in FABQ U1 to U7 [-] ITT
End point description:	
U1 -- Baseline U7 -- 42 days postop	
End point type	Primary
End point timeframe:	
U1 - U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	12	17	
Units: [-]				
arithmetic mean (standard deviation)	-6.82 (± 16.84)	-11.17 (± 28.70)	-9.89 (± 25.32)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	17
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.758 [10]
Method	t-test, 2-sided

Notes:

[10] - purely descriptive

Primary: Change in FABQ U1 to U8 [-] ITT

End point title	Change in FABQ U1 to U8 [-] ITT
End point description:	
U1 -- Baseline U8 -- 84 days postop	
End point type	Primary

End point timeframe: U1 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	10	14	
Units: [-]				
median (inter-quartile range (Q1-Q3))	0.00 (-6.82 to 0.00)	-13.64 (-28.79 to 0.00)	-5.30 (-19.70 to 0.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	14
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.32 [11]
Method	Wilcoxon (Mann-Whitney)

Notes:
[11] - purely descriptive

Primary: Change in FABQ-subscore work U1 to U2 [-] ITT

End point title	Change in FABQ-subscore work U1 to U2 [-] ITT
End point description: U1 -- Baseline U2 -- 1 day preop	
End point type	Primary
End point timeframe: U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	6	15	21	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-1.19 (-5.95 to 1.19)	0.00 (-9.52 to 2.38)	0.00 (-7.14 to 1.19)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.953 [12]
Method	Wilcoxon (Mann-Whitney)

Notes:

[12] - purely descriptive

Primary: Change in FABQ-subscore work U1 to U7 [-] ITT

End point title	Change in FABQ-subscore work U1 to U7 [-] ITT
End point description:	
U1 -- Baseline U7 -- 42 days postop	
End point type	Primary
End point timeframe:	
U1 - U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	12	17	
Units: [-]				
arithmetic mean (standard deviation)	-9.76 (± 14.54)	-10.02 (± 31.45)	-9.94 (± 27.07)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	17
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.986 [13]
Method	t-test, 2-sided

Notes:

[13] - purely descriptive

Primary: Change in FABQ-subscore work U1 to U8 [-] ITT

End point title	Change in FABQ-subscore work U1 to U8 [-] ITT
End point description:	
U1 -- Baseline U8 -- 84 days postop	
End point type	Primary

End point timeframe:
U1 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	10	15	
Units: [-]				
median (inter-quartile range (Q1-Q3))	0.00 (-9.52 to 0.00)	-1.19 (-33.33 to 7.14)	0.00 (-23.81 to 2.38)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Nabilone (V-Gruppe) v Placebo (K-Gruppe)
Number of subjects included in analysis	15
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.838 [14]
Method	Wilcoxon (Mann-Whitney)

Notes:
[14] - purely descriptive

Primary: Change in FABQ-subscore physical activity U1 to U2 [-] ITT

End point title	Change in FABQ-subscore physical activity U1 to U2 [-] ITT
End point description: U1 -- Baseline U2 --1 day preop	
End point type	Primary
End point timeframe: U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	8	20	28	
Units: [-]				
median (inter-quartile range (Q1-Q3))	0.00 (-6.25 to 2.08)	0.00 (-8.33 to 14.58)	0.00 (-6.25 to 4.17)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.584 [15]
Method	Wilcoxon (Mann-Whitney)

Notes:

[15] - purely descriptive

Primary: Change in FABQ-subscore physical activity U1 to U7 [-] ITT	
End point title	Change in FABQ-subscore physical activity U1 to U7 [-] ITT
End point description: U1 -- Baseline U7 -- 42 days postop	
End point type	Primary
End point timeframe: U1 - U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	15	22	
Units: [-]				
arithmetic mean (standard deviation)	-14.29 (± 24.16)	-8.06 (± 32.79)	-10.04 (± 29.87)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.66 [16]
Method	t-test, 2-sided

Notes:

[16] - purely descriptive

Primary: Change in FABQ-subscore physical activity U1 to U8 [-] ITT	
End point title	Change in FABQ-subscore physical activity U1 to U8 [-] ITT
End point description: U1 -- Baseline U8 -- 84 days postop	
End point type	Primary

End point timeframe: U1 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	12	19	
Units: [-]				
arithmetic mean (standard deviation)	-4.76 (± 18.39)	-14.58 (± 26.56)	-10.96 (± 23.82)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	19
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.401 [17]
Method	t-test, 2-sided

Notes:
[17] - purely descriptive

Primary: Change in pinprick pain threshold U1 to U2 [mN] ITT

End point title	Change in pinprick pain threshold U1 to U2 [mN] ITT
End point description: U1 -- Baseline U2 -- 1 day preop	
End point type	Primary
End point timeframe: U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	20	31	
Units: [mN]				
arithmetic mean (standard deviation)	19.54 (± 69.14)	28.33 (± 94.14)	25.21 (± 85.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Nabilone (V-Gruppe) v Placebo (K-Gruppe)
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.788 [18]
Method	t-test, 2-sided

Notes:

[18] - purely descriptive

Primary: Change in pinprick pain threshold U1 to U3 [mN] ITT	
End point title	Change in pinprick pain threshold U1 to U3 [mN] ITT
End point description: U1 -- Baseline U3 -- 2 days postop	
End point type	Primary
End point timeframe: U1 - U3	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	22	33	
Units: [mN]				
arithmetic mean (standard deviation)	-10.36 (± 117.58)	2.71 (± 88.09)	-1.65 (± 97.22)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.722 [19]
Method	t-test, 2-sided

Notes:

[19] - purely descriptive

Primary: Change in pinprick pain threshold U1 to U4 [mN] ITT	
End point title	Change in pinprick pain threshold U1 to U4 [mN] ITT
End point description: U1 -- Baseline U4 -- 5 days postop	
End point type	Primary

End point timeframe: U1 - U4

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	21	32	
Units: [mN]				
arithmetic mean (standard deviation)	-31.55 (± 131.39)	-15.43 (± 120.12)	-20.97 (± 122.22)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.729 [20]
Method	t-test, 2-sided

Notes:
[20] - purely descriptive

Primary: Change in pinprick pain threshold U1 to U5 [mN] ITT

End point title	Change in pinprick pain threshold U1 to U5 [mN] ITT
End point description: U1 -- Baseline U5 -- Dismissal day (not before postop day 6)	
End point type	Primary
End point timeframe: U1 - U5	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	19	30	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	-25.11 (-57.47 to 144.57)	0.00 (-47.43 to 82.58)	-6.28 (-47.43 to 82.58)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.841 [21]
Method	Wilcoxon (Mann-Whitney)

Notes:

[21] - purely descriptive

Primary: Change in pinprick pain threshold U1 to U7 [mN] ITT	
End point title	Change in pinprick pain threshold U1 to U7 [mN] ITT
End point description: U1 -- Baseline U7 -- 42 days postop	
End point type	Primary
End point timeframe: U1 - U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	9	12	21	
Units: [mN]				
arithmetic mean (standard deviation)	12.38 (± 78.99)	18.57 (± 68.78)	15.91 (± 71.47)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85 [22]
Method	t-test, 2-sided

Notes:

[22] - purely descriptive

Primary: Change in pinprick pain threshold U1 to U8 [mN] ITT	
End point title	Change in pinprick pain threshold U1 to U8 [mN] ITT
End point description: U1 -- Baseline U8 -- 84 days postop	
End point type	Primary

End point timeframe:
U1 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	11	18	
Units: [mN]				
arithmetic mean (standard deviation)	2.16 (± 73.68)	48.91 (± 80.60)	30.73 (± 79.30)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	18
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.233 [23]
Method	t-test, 2-sided

Notes:
[23] - purely descriptive

Primary: Change in SF36 mental sum score U1 to U2 [-] ITT

End point title	Change in SF36 mental sum score U1 to U2 [-] ITT

End point description:
U1 -- Baseline
U2 -- 1 day preop

End point type	Primary

End point timeframe:
U1 - U2

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	23	33	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-1.80 (-3.93 to 1.00)	0.55 (-8.34 to 6.99)	0.31 (-7.98 to 3.60)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.603 [24]
Method	Wilcoxon (Mann-Whitney)

Notes:

[24] - purely descriptive

Primary: Change in SF36 mental sum score U1 to U7 [-] ITT	
End point title	Change in SF36 mental sum score U1 to U7 [-] ITT
End point description:	
U1 -- Baseline U7 -- 42 days postop	
End point type	Primary
End point timeframe:	
U1 - U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	16	26	
Units: [-]				
arithmetic mean (standard deviation)	5.49 (± 12.53)	3.70 (± 14.91)	4.39 (± 13.81)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.755 [25]
Method	t-test, 2-sided

Notes:

[25] - purely descriptive

Primary: Change in SF36 mental sum score U1 to U8 [-] ITT	
End point title	Change in SF36 mental sum score U1 to U8 [-] ITT
End point description:	
U1 -- Baseline U8 -- 84 days postop	
End point type	Primary
End point timeframe:	
U1 - U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	9	14	23	
Units: [-]				
arithmetic mean (standard deviation)	2.31 (± 12.73)	7.44 (± 12.72)	5.43 (± 12.69)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.356 [26]
Method	t-test, 2-sided

Notes:

[26] - purely descriptive

Primary: Change in SF36 physical sum score U1 to U2 [-] ITT

End point title	Change in SF36 physical sum score U1 to U2 [-] ITT
End point description: U1 -- Baseline U2 -- 1 day preop	
End point type	Primary
End point timeframe: U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	23	33	
Units: [-]				
arithmetic mean (standard deviation)	2.76 (± 4.45)	0.28 (± 4.65)	1.03 (± 4.66)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.163 [27]
Method	t-test, 2-sided

Notes:

[27] - purely descriptive

Primary: Change in SF36 physical sum score U1 to U7 [-] ITT

End point title	Change in SF36 physical sum score U1 to U7 [-] ITT

End point description:

U1 -- Baseline
U7 -- 42 days postop

End point type	Primary

End point timeframe:

U1 - U7

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	16	26	
Units: [-]				
median (inter-quartile range (Q1-Q3))	8.07 (3.37 to 11.82)	3.66 (2.01 to 9.49)	5.10 (2.30 to 11.82)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.391 [28]
Method	Wilcoxon (Mann-Whitney)

Notes:

[28] - purely descriptive

Primary: Change in SF36 physical sum score U1 to U8 [-] ITT

End point title	Change in SF36 physical sum score U1 to U8 [-] ITT

End point description:

U1 -- Baseline
U8 -- 84 days postop

End point type	Primary

End point timeframe:

U1 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	9	14	23	
Units: [-]				
arithmetic mean (standard deviation)	12.45 (± 8.60)	8.59 (± 8.20)	10.10 (± 8.39)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.292 [29]
Method	t-test, 2-sided

Notes:

[29] - purely descriptive

Primary: Change in HADS anxiety U1 to U2 [-] PP

End point title	Change in HADS anxiety U1 to U2 [-] PP
End point description:	
U1 -- Baseline U2 -- 1 day preop	
End point type	Primary
End point timeframe:	
U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-1.00 (-2.00 to 1.00)	-1.00 (-2.00 to 4.00)	-1.00 (-2.00 to 1.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.949 [30]
Method	Wilcoxon (Mann-Whitney)

Notes:

[30] - purely descriptive

Primary: Change in HADS anxiety U1 to U7 [-] PP

End point title	Change in HADS anxiety U1 to U7 [-] PP
End point description:	
U1 -- Baseline U7 -- 42 days postop	
End point type	Primary
End point timeframe:	
U1 - U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-3.00 (-5.00 to -1.00)	-3.00 (-6.00 to 0.00)	-3.00 (-6.00 to 0.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.868 [31]
Method	Wilcoxon (Mann-Whitney)

Notes:

[31] - purely descriptive

Primary: Change in HADS anxiety U1 to U8 [-] PP

End point title	Change in HADS anxiety U1 to U8 [-] PP
End point description:	
U1 -- Baseline U8 -- 84 days postop	
End point type	Primary
End point timeframe:	
U1 - U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	13	23	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-1.00 (-3.00 to 2.00)	-1.00 (-5.00 to -1.00)	-1.00 (-3.00 to 0.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.285 [32]
Method	Wilcoxon (Mann-Whitney)

Notes:

[32] - purely descriptive

Primary: Change in HADS depression U1 to U2 [-] PP

End point title	Change in HADS depression U1 to U2 [-] PP
End point description:	
U1 -- Baseline U2 -- 1 day preop	
End point type	Primary
End point timeframe:	
U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
median (inter-quartile range (Q1-Q3))	0.00 (-1.00 to 3.00)	1.00 (-1.00 to 4.00)	0.00 (-1.00 to 3.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.428 [33]
Method	Wilcoxon (Mann-Whitney)

Notes:

[33] - purely descriptive

Primary: Change in HADS depression U1 to U7 [-] PP

End point title	Change in HADS depression U1 to U7 [-] PP
End point description:	
U1 -- Baseline U7 -- 42 days postop	
End point type	Primary
End point timeframe:	
U1 - U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-1.00 (-5.00 to -1.00)	-1.00 (-3.00 to 0.00)	-1.00 (-4.00 to 0.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.708 [34]
Method	Wilcoxon (Mann-Whitney)

Notes:

[34] - purely descriptive

Primary: Change in HADS depression U1 to U8 [-] PP

End point title	Change in HADS depression U1 to U8 [-] PP
End point description:	
U1 -- Baseline U8 -- 84 days postop	
End point type	Primary
End point timeframe:	
U1 - U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	13	23	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-2.00 (-2.00 to 2.00)	-2.00 (-3.00 to -1.00)	-2.00 (-3.00 to -1.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.749 [35]
Method	Wilcoxon (Mann-Whitney)

Notes:

[35] - purely descriptive

Primary: Change in Oswestry Low Back Pain Disability Questionaire U1 to U2 [%] PP

End point title	Change in Oswestry Low Back Pain Disability Questionaire U1 to U2 [%] PP
End point description: U1 -- Baseline U2 -- 1 day preop	
End point type	Primary
End point timeframe: U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [%]				
median (inter-quartile range (Q1-Q3))	-6.00 (-6.67 to -1.11)	-2.22 (-5.11 to 2.00)	-2.22 (-6.67 to 0.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.348 [36]
Method	Wilcoxon (Mann-Whitney)

Notes:

[36] - purely descriptive

Primary: Change in Oswestry Low Back Pain Disability Questionaire U1 to U7 [%] PP

End point title	Change in Oswestry Low Back Pain Disability Questionaire U1 to U7 [%] PP

End point description:

U1 -- Baseline
U7 -- 42 days postop

End point type	Primary

End point timeframe:

U1 - U7

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [%]				
median (inter-quartile range (Q1-Q3))	-11.11 (-28.00 to -4.00)	-11.11 (-20.00 to 2.22)	-11.11 (-22.22 to -0.67)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.391 [37]
Method	Wilcoxon (Mann-Whitney)

Notes:

[37] - purely descriptive

Primary: Change in Oswestry Low Back Pain Disability Questionaire U1 to U8 [%] PP

End point title	Change in Oswestry Low Back Pain Disability Questionaire U1 to U8 [%] PP

End point description:

U1 -- Baseline

U8 -- 84 days postop

End point type	Primary

End point timeframe:

U1 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	13	23	
Units: [%]				
median (inter-quartile range (Q1-Q3))	-23.56 (-26.00 to -16.00)	-9.33 (-20.00 to -4.00)	-17.56 (-26.00 to -4.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.152 [38]
Method	Wilcoxon (Mann-Whitney)

Notes:

[38] - purely descriptive

Primary: Change in FABQ U1 to U2 [-] PP

End point title	Change in FABQ U1 to U2 [-] PP

End point description:

U1 -- Baseline
U2 -- 1 day preop

End point type	Primary

End point timeframe:

U1 - U2

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	9	14	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-3.03 (-3.79 to -1.52)	0.00 (-6.06 to 6.06)	-1.52 (-6.06 to 0.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Nabilone (V-Gruppe) v Placebo (K-Gruppe)
Number of subjects included in analysis	14
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.313 [39]
Method	Wilcoxon (Mann-Whitney)

Notes:

[39] - purely descriptive

Primary: Change in FABQ U1 to U7 [-] PP

End point title	Change in FABQ U1 to U7 [-] PP

End point description:

U1 -- Baseline
U7 -- 42 days postop

End point type	Primary

End point timeframe:

U1 - U7

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	11	16	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-1.52 (-16.67 to 1.52)	-7.58 (-31.82 to 9.09)	-7.58 (-25.00 to 5.30)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	16
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.643 [40]
Method	Wilcoxon (Mann-Whitney)

Notes:

[40] - purely descriptive

Primary: Change in FABQ U1 to U8 [-] PP

End point title	Change in FABQ U1 to U8 [-] PP

End point description:

U1 -- Baseline
U8 -- 84 days postop

End point type	Primary

End point timeframe:
U1 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	9	13	
Units: [-]				
median (inter-quartile range (Q1-Q3))	0.00 (-6.82 to 0.00)	-9.09 (-19.70 to 0.00)	-1.52 (-18.18 to 0.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	13
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.432 [41]
Method	Wilcoxon (Mann-Whitney)

Notes:
[41] - purely descriptive

Primary: Change in FABQ-subscore work U1 to U2 [-] PP

End point title	Change in FABQ-subscore work U1 to U2 [-] PP

End point description:
U1 -- Baseline
U2 -- 1 day preop

End point type	Primary

End point timeframe:
U1 - U2

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	6	10	16	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-1.19 (-5.95 to 1.19)	0.00 (-9.52 to 2.38)	0.00 (-8.33 to 1.79)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	16
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.852 [42]
Method	Wilcoxon (Mann-Whitney)

Notes:

[42] - purely descriptive

Primary: Change in FABQ-subscore work U1 to U7 [-] PP	
End point title	Change in FABQ-subscore work U1 to U7 [-] PP
End point description: U1 -- Baseline U7 -- 42 days postop	
End point type	Primary
End point timeframe: U1 - U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	11	16	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-17.86 (-19.05 to 4.76)	0.00 (-38.10 to 7.14)	-4.76 (-21.43 to 5.95)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	16
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.893 [43]
Method	Wilcoxon (Mann-Whitney)

Notes:

[43] - purely descriptive

Primary: Change in FABQ-subscore work U1 to U8 [-] PP	
End point title	Change in FABQ-subscore work U1 to U8 [-] PP
End point description: U1 -- Baseline U8 -- 84 days postop	
End point type	Primary

End point timeframe:
U1 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	9	14	
Units: [-]				
median (inter-quartile range (Q1-Q3))	0.00 (-9.52 to 0.00)	0.00 (-23.81 to 7.14)	0.00 (-17.86 to 2.38)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	14
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.982 [44]
Method	Wilcoxon (Mann-Whitney)

Notes:
[44] - purely descriptive

Primary: Change in FABQ-subscore physical activity U1 to U2 [-] PP

End point title	Change in FABQ-subscore physical activity U1 to U2 [-] PP

End point description:
U1 -- Baseline
U2 -- 1 day preop

End point type	Primary

End point timeframe:
U1 - U2

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	8	13	21	
Units: [-]				
median (inter-quartile range (Q1-Q3))	0.00 (-6.25 to 2.08)	0.00 (-12.50 to 4.17)	0.00 (-8.33 to 4.17)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Nabilone (V-Gruppe) v Placebo (K-Gruppe)
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.928 [45]
Method	Wilcoxon (Mann-Whitney)

Notes:

[45] - purely descriptive

Primary: Change in FABQ-subscore physical activity U1 to U7 [-] PP	
End point title	Change in FABQ-subscore physical activity U1 to U7 [-] PP
End point description: U1 -- Baseline U7 -- 42 days postop	
End point type	Primary
End point timeframe: U1 - U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	14	21	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-12.50 (-41.67 to -4.17)	0.00 (-33.33 to 20.83)	-4.17 (-33.33 to 8.33)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.368 [46]
Method	Wilcoxon (Mann-Whitney)

Notes:

[46] - purely descriptive

Primary: Change in FABQ-subscore physical activity U1 to U8 [-] PP	
End point title	Change in FABQ-subscore physical activity U1 to U8 [-] PP
End point description: U1 -- Baseline U8 -- 84 days postop	
End point type	Primary

End point timeframe:
U1 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	11	18	
Units: [-]				
median (inter-quartile range (Q1-Q3))	0.00 (-20.83 to 0.00)	0.00 (-37.50 to 12.50)	0.00 (-33.33 to 0.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	18
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.634 [47]
Method	Wilcoxon (Mann-Whitney)

Notes:
[47] - purely descriptive

Primary: Change in pinprick pain threshold U1 to U2 [mN] PP	
End point title	Change in pinprick pain threshold U1 to U2 [mN] PP
End point description: U1 -- Baseline U2 -- 1 day preop	
End point type	Primary
End point timeframe: U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	13	23	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	6.28 (-38.07 to 50.03)	0.00 (-40.90 to 81.79)	0.00 (-40.90 to 81.79)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.82 [48]
Method	Wilcoxon (Mann-Whitney)

Notes:

[48] - purely descriptive

Primary: Change in pinprick pain threshold U1 to U3 [mN] PP

End point title	Change in pinprick pain threshold U1 to U3 [mN] PP
End point description:	
U1 -- Baseline U3 -- 2 days postop	
End point type	Primary
End point timeframe:	
U1 - U3	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	14	25	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	12.56 (-71.89 to 93.96)	-15.80 (-61.99 to 97.01)	-12.56 (-64.00 to 93.96)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.767 [49]
Method	Wilcoxon (Mann-Whitney)

Notes:

[49] - purely descriptive

Primary: Change in pinprick pain threshold U1 to U4 [mN] PP

End point title	Change in pinprick pain threshold U1 to U4 [mN] PP
End point description:	
U1 -- Baseline U4 -- 5 days postop	
End point type	Primary

End point timeframe:
U1 - U4

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	14	25	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	-40.90 (-100.06 to 35.60)	-24.25 (-77.19 to 21.86)	-40.90 (-82.58 to 21.86)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.82 [50]
Method	Wilcoxon (Mann-Whitney)

Notes:
[50] - purely descriptive

Primary: Change in pinprick pain threshold U1 to U5 [mN] PP

End point title	Change in pinprick pain threshold U1 to U5 [mN] PP
End point description:	
U1 -- Baseline U5 -- Dismissal day (not before postop day 6)	
End point type	Primary
End point timeframe:	
U1 - U5	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	-25.11 (-57.47 to 144.57)	-12.56 (-54.78 to 82.58)	-18.84 (-54.78 to 82.58)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.909 [51]
Method	Wilcoxon (Mann-Whitney)

Notes:

[51] - purely descriptive

Primary: Change in pinprick pain threshold U1 to U7 [mN] PP	
End point title	Change in pinprick pain threshold U1 to U7 [mN] PP
End point description: U1 -- Baseline U7 -- 42 days postop	
End point type	Primary
End point timeframe: U1 - U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	9	12	21	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	0.00 (-43.73 to 25.11)	13.49 (-18.14 to 52.00)	0.00 (-21.86 to 50.03)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.688 [52]
Method	Wilcoxon (Mann-Whitney)

Notes:

[52] - purely descriptive

Primary: Change in pinprick pain threshold U1 to U8 [mN] PP	
End point title	Change in pinprick pain threshold U1 to U8 [mN] PP
End point description: U1 -- Baseline U8 -- 84 days postop	
End point type	Primary

End point timeframe:
U1 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	10	17	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	0.00 (-14.42 to 50.23)	38.07 (-21.86 to 71.21)	30.99 (-14.42 to 57.47)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	17
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.402 [53]
Method	Wilcoxon (Mann-Whitney)

Notes:
[53] - purely descriptive

Primary: Change in SF36 mental sum score U1 to U2 [-] PP

End point title	Change in SF36 mental sum score U1 to U2 [-] PP

End point description:
U1 -- Baseline
U2 -- 1 day preop

End point type	Primary

End point timeframe:
U1 - U2

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	15	25	
Units: [-]				
median (inter-quartile range (Q1-Q3))	-1.80 (-3.93 to 1.00)	1.25 (-6.16 to 7.28)	0.68 (-3.93 to 3.60)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.196 [54]
Method	Wilcoxon (Mann-Whitney)

Notes:

[54] - purely descriptive

Primary: Change in SF36 mental sum score U1 to U7 [-] PP

End point title	Change in SF36 mental sum score U1 to U7 [-] PP
End point description:	
U1 -- Baseline U7 -- 42 days postop	
End point type	Primary
End point timeframe:	
U1 - U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	15	25	
Units: [-]				
median (inter-quartile range (Q1-Q3))	4.58 (-1.34 to 12.70)	3.22 (-7.54 to 18.43)	3.22 (-2.33 to 14.90)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.849 [55]
Method	Wilcoxon (Mann-Whitney)

Notes:

[55] - purely descriptive

Primary: Change in SF36 mental sum score U1 to U8 [-] PP

End point title	Change in SF36 mental sum score U1 to U8 [-] PP
End point description:	
U1 -- Baseline U8 -- 84 days postop	
End point type	Primary

End point timeframe:
U1 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	9	13	22	
Units: [-]				
median (inter-quartile range (Q1-Q3))	0.88 (-5.54 to 11.11)	2.88 (-1.68 to 15.10)	2.42 (-4.74 to 14.43)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.393 [56]
Method	Wilcoxon (Mann-Whitney)

Notes:
[56] - purely descriptive

Primary: Change in SF36 physical sum score U1 to U2 [-] PP

End point title	Change in SF36 physical sum score U1 to U2 [-] PP

End point description:
U1 -- Baseline
U2 -- 1 day preop

End point type	Primary

End point timeframe:
U1 - U2

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	15	25	
Units: [-]				
median (inter-quartile range (Q1-Q3))	1.29 (-1.34 to 6.03)	0.11 (-2.19 to 3.54)	0.72 (-1.34 to 3.78)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.304 [57]
Method	Wilcoxon (Mann-Whitney)

Notes:

[57] - purely descriptive

Primary: Change in SF36 physical sum score U1 to U7 [-] PP

End point title	Change in SF36 physical sum score U1 to U7 [-] PP
End point description:	
U1 -- Baseline U7 -- 42 days postop	
End point type	Primary
End point timeframe:	
U1 - U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	15	25	
Units: [-]				
median (inter-quartile range (Q1-Q3))	8.07 (3.37 to 11.82)	2.96 (1.71 to 12.45)	4.41 (2.30 to 11.82)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.397 [58]
Method	Wilcoxon (Mann-Whitney)

Notes:

[58] - purely descriptive

Primary: Change in SF36 physical sum score U1 to U8 [-] PP

End point title	Change in SF36 physical sum score U1 to U8 [-] PP
End point description:	
U1 -- Baseline U8 -- 84 days postop	
End point type	Primary

End point timeframe:
U1 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	9	13	22	
Units: [-]				
median (inter-quartile range (Q1-Q3))	11.96 (6.55 to 17.77)	7.17 (1.62 to 9.44)	8.19 (3.70 to 17.77)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.324 [59]
Method	Wilcoxon (Mann-Whitney)

Notes:
[59] - purely descriptive

Secondary: HADS anxiety at U2 [-] ITT

End point title	HADS anxiety at U2 [-] ITT

End point description:
U2 -- 1 day preop

End point type	Secondary

End point timeframe:
U2

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	23	34	
Units: [-]				
median (inter-quartile range (Q1-Q3))	4.00 (2.00 to 8.00)	7.00 (5.00 to 15.00)	7.00 (4.00 to 13.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.088 [60]
Method	Wilcoxon (Mann-Whitney)

Notes:
[60] - purely descriptive

Secondary: HADS anxiety at U7 [-] ITT	
End point title	HADS anxiety at U7 [-] ITT
End point description: U7 -- 42 days postop	
End point type	Secondary
End point timeframe: U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	16	27	
Units: [-]				
median (inter-quartile range (Q1-Q3))	3.00 (1.00 to 4.00)	3.50 (1.00 to 8.00)	3.00 (1.00 to 7.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.467 [61]
Method	Wilcoxon (Mann-Whitney)

Notes:
[61] - purely descriptive

Secondary: HADS anxiety at U8 [-] ITT	
End point title	HADS anxiety at U8 [-] ITT
End point description: U8 -- 84 days postop	
End point type	Secondary
End point timeframe: U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	14	24	
Units: [-]				
median (inter-quartile range (Q1-Q3))	3.00 (2.00 to 6.00)	4.50 (2.00 to 6.00)	3.50 (2.00 to 6.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.592 [62]
Method	Wilcoxon (Mann-Whitney)

Notes:
[62] - purely descriptive

Secondary: HADS depression at U2 [-] ITT

End point title	HADS depression at U2 [-] ITT
End point description: U2 -- 1 day preop	
End point type	Secondary
End point timeframe: U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	23	34	
Units: [-]				
arithmetic mean (standard deviation)	5.36 (± 2.98)	8.83 (± 5.59)	7.71 (± 5.12)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.025 [63]
Method	t-test, 2-sided

Notes:
[63] - purely descriptive

Secondary: HADS depression at U7 [-] ITT

End point title	HADS depression at U7 [-] ITT

End point description:
U7 -- 42 days postop

End point type	Secondary

End point timeframe:
U7

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	16	27	
Units: [-]				
median (inter-quartile range (Q1-Q3))	2.00 (2.00 to 3.00)	3.00 (2.50 to 8.50)	3.00 (2.00 to 7.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.191 [64]
Method	Wilcoxon (Mann-Whitney)

Notes:
[64] - purely descriptive

Secondary: HADS depression at U8 [-] ITT

End point title	HADS depression at U8 [-] ITT

End point description:
U8 -- 84 days postop

End point type	Secondary

End point timeframe:
U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	14	24	
Units: [-]				
arithmetic mean (standard deviation)	3.60 (± 3.63)	5.71 (± 4.41)	4.83 (± 4.16)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.227 [65]
Method	t-test, 2-sided

Notes:
[65] - purely descriptive

Secondary: SF36 mental sum score at U2 [-] ITT

End point title	SF36 mental sum score at U2 [-] ITT
End point description: U2 -- 1 day preop	
End point type	Secondary
End point timeframe: U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	23	34	
Units: [-]				
arithmetic mean (standard deviation)	41.85 (± 14.43)	34.50 (± 19.22)	36.88 (± 17.93)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.27 [66]
Method	t-test, 2-sided

Notes:
[66] - purely descriptive

Secondary: SF36 mental sum score at U7 [-] ITT

End point title	SF36 mental sum score at U7 [-] ITT

End point description:
U7 -- 42 days postop

End point type	Secondary

End point timeframe:
U7

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	16	27	
Units: [-]				
median (inter-quartile range (Q1-Q3))	47.20 (40.99 to 60.81)	46.01 (26.66 to 50.57)	46.28 (37.76 to 52.49)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.178 [67]
Method	Wilcoxon (Mann-Whitney)

Notes:
[67] - purely descriptive

Secondary: SF36 mental sum score at U8 [-] ITT

End point title	SF36 mental sum score at U8 [-] ITT

End point description:
U8 -- 84 days postop

End point type	Secondary

End point timeframe:
U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	14	24	
Units: [-]				
median (inter-quartile range (Q1-Q3))	47.26 (42.72 to 57.86)	48.61 (27.77 to 53.58)	48.38 (36.55 to 55.71)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.666 [68]
Method	Wilcoxon (Mann-Whitney)

Notes:
[68] - purely descriptive

Secondary: SF36 physical sum score at U2 [-] ITT

End point title	SF36 physical sum score at U2 [-] ITT
End point description: U2 -- 1 day preop	
End point type	Secondary
End point timeframe: U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	23	34	
Units: [-]				
arithmetic mean (standard deviation)	26.37 (± 7.61)	31.63 (± 6.47)	29.93 (± 7.19)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.044 [69]
Method	t-test, 2-sided

Notes:
[69] - purely descriptive

Secondary: SF36 physical sum score at U7 [-] ITT

End point title	SF36 physical sum score at U7 [-] ITT
End point description: U7 -- 42 days postop	
End point type	Secondary
End point timeframe: U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	16	27	
Units: [-]				
arithmetic mean (standard deviation)	32.11 (± 8.00)	37.93 (± 6.27)	35.56 (± 7.47)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.044 [70]
Method	t-test, 2-sided

Notes:
[70] - purely descriptive

Secondary: SF36 physical sum score at U8 [-] ITT

End point title	SF36 physical sum score at U8 [-] ITT
End point description: U8 -- 84 days postop	
End point type	Secondary
End point timeframe: U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	14	24	
Units: [-]				
arithmetic mean (standard deviation)	36.34 (± 10.27)	38.80 (± 10.41)	37.77 (± 10.20)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.572 [71]
Method	t-test, 2-sided

Notes:

[71] - purely descriptive

Secondary: Oswestry Disability Questionnaire Low Back Pain at U2 [%] ITT

End point title	Oswestry Disability Questionnaire Low Back Pain at U2 [%] ITT
End point description: U2 -- 1 day preop	
End point type	Secondary
End point timeframe: U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	23	34	
Units: [%]				
median (inter-quartile range (Q1-Q3))	42.00 (36.00 to 55.56)	44.44 (40.00 to 51.11)	44.22 (37.14 to 51.11)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.592 [72]
Method	Wilcoxon (Mann-Whitney)

Notes:
[72] - purely descriptive

Secondary: Oswestry Disability Questionnaire Low Back Pain at U7 [%] ITT

End point title	Oswestry Disability Questionnaire Low Back Pain at U7 [%] ITT
End point description: U7 -- 42 days postop	
End point type	Secondary
End point timeframe: U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	16	27	
Units: [%]				
arithmetic mean (standard deviation)	32.51 (± 13.59)	36.58 (± 18.71)	34.92 (± 16.65)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.542 [73]
Method	t-test, 2-sided

Notes:
[73] - purely descriptive

Secondary: Oswestry Disability Questionnaire Low Back Pain at U8 [%] ITT

End point title	Oswestry Disability Questionnaire Low Back Pain at U8 [%] ITT
End point description: U8 -- 84 days postop	
End point type	Secondary
End point timeframe: U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	14	24	
Units: [%]				
arithmetic mean (standard deviation)	26.09 (± 17.09)	33.83 (± 16.25)	30.60 (± 16.69)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.273 [74]
Method	t-test, 2-sided

Notes:
[74] - purely descriptive

Secondary: Pinprick pain threshold at U2 [mN] ITT

End point title	Pinprick pain threshold at U2 [mN] ITT
End point description: U2 -- 1 day preop	
End point type	Secondary
End point timeframe: U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	20	31	
Units: [mN]				
arithmetic mean (standard deviation)	199.28 (± 87.86)	199.39 (± 105.52)	199.35 (± 98.11)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.998 [75]
Method	t-test, 2-sided

Notes:
[75] - purely descriptive

Secondary: Pinprick pain threshold at U3 [mN] ITT

End point title	Pinprick pain threshold at U3 [mN] ITT
End point description: U3 -- 2 days postop	
End point type	Secondary
End point timeframe: U3	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	22	33	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	147.03 (97.01 to 168.90)	157.97 (97.01 to 256.00)	147.03 (97.01 to 222.86)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.602 [76]
Method	Wilcoxon (Mann-Whitney)

Notes:
[76] - purely descriptive

Secondary: Pinprick pain threshold at U4 [mN] ITT

End point title	Pinprick pain threshold at U4 [mN] ITT
End point description: U4 -- 5 days postop	
End point type	Secondary
End point timeframe: U4	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	21	32	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	111.43 (97.01 to 194.01)	168.90 (97.01 to 194.01)	128.00 (97.01 to 194.01)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.51 [77]
Method	Wilcoxon (Mann-Whitney)

Notes:
[77] - purely descriptive

Secondary: Pinprick pain threshold at U5 [mN] ITT

End point title	Pinprick pain threshold at U5 [mN] ITT
End point description: U5 -- Dismissal day (not before postop day 6)	
End point type	Secondary
End point timeframe: U5	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	19	32	
Units: [mN]				
arithmetic mean (standard deviation)	169.87 (± 79.75)	185.71 (± 90.77)	179.90 (± 85.83)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.635 [78]
Method	t-test, 2-sided

Notes:
[78] - purely descriptive

Secondary: Pinprick pain threshold at U7 [mN] ITT

End point title	Pinprick pain threshold at U7 [mN] ITT
End point description: U7 -- 42 days postop	
End point type	Secondary
End point timeframe: U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	9	12	21	
Units: [mN]				
arithmetic mean (standard deviation)	201.11 (± 61.04)	182.49 (± 72.40)	190.47 (± 66.80)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.541 [79]
Method	t-test, 2-sided

Notes:
[79] - purely descriptive

Secondary: Pinprick pain threshold at U8 [mN] ITT

End point title	Pinprick pain threshold at U8 [mN] ITT
End point description: U8 -- 84 days postop	
End point type	Secondary
End point timeframe: U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	11	18	
Units: [mN]				
arithmetic mean (standard deviation)	203.25 (± 122.63)	214.34 (± 107.80)	210.03 (± 110.34)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	18
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.842 [80]
Method	t-test, 2-sided

Notes:

[80] - purely descriptive

Secondary: Weak opioid medication from U1 until U2 [categorized] ITT

End point title	Weak opioid medication from U1 until U2 [categorized] ITT
End point description:	
U1 -- Baseline U2 -- 1 day preop	
End point type	Secondary
End point timeframe:	
U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	12	23	35	
Units: [-]				
Not received	10	15	25	
Lower dose compared to standard pain management pr	0	2	2	
Dose according to standard pain management protoco	1	3	4	
Higher dose compared to standard pain management p	1	3	4	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.393 [81]
Method	Wilcoxon (Mann-Whitney)

Notes:

[81] - purely descriptive

Secondary: Strong opioid medication from U1 until U2 [categorized] ITT

End point title	Strong opioid medication from U1 until U2 [categorized] ITT
End point description:	
U1 -- Baseline U2 -- 1 day preop	
End point type	Secondary
End point timeframe:	
U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	12	23	35	
Units: [-]				
Not received	9	18	27	
Lower dose compared to standard pain management pr	0	0	0	
Dose according to standard pain management protoco	2	3	5	
Higher dose compared to standard pain management p	1	2	3	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Nabilone (V-Gruppe) v Placebo (K-Gruppe)
Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.944 [82]
Method	Wilcoxon (Mann-Whitney)

Notes:

[82] - purely descriptive

Secondary: Non-opioid medication from U1 until U2 [categorized] ITT

End point title	Non-opioid medication from U1 until U2 [categorized] ITT
End point description: U1 -- Baseline U2 -- 1 day preop	
End point type	Secondary
End point timeframe: U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	12	23	35	
Units: [-]				
Not received	5	13	18	
Lower dose compared to standard pain management pr	5	6	11	
Dose according to standard pain management protoco	2	2	4	
Higher dose compared to standard pain management p	0	2	2	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.616 [83]
Method	Wilcoxon (Mann-Whitney)

Notes:
[83] - purely descriptive

Secondary: Weak opioid medication from OP until U5 [categorized] ITT	
End point title	Weak opioid medication from OP until U5 [categorized] ITT
End point description: OP -- end of surgery U5 -- Dismissal day (not before postop day 6)	
End point type	Secondary
End point timeframe: OP - U5	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	20	31	
Units: [-]				
Not received	4	2	6	
Lower dose compared to standard pain management pr	0	6	6	
Dose according to standard pain management protoco	6	11	17	
Higher dose compared to standard pain management p	1	1	2	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.804 [84]
Method	Wilcoxon (Mann-Whitney)

Notes:

[84] - purely descriptive

Secondary: Strong opioid medication from OP until U5 [categorized] ITT

End point title	Strong opioid medication from OP until U5 [categorized] ITT
End point description:	
OP -- end of surgery U5 -- Dismissal day (not before postop day 6)	
End point type	Secondary
End point timeframe:	
OP - U5	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	19	30	
Units: [-]				
Not received	0	0	0	
Lower dose compared to standard pain management pr	0	0	0	
Dose according to standard pain management protoco	8	16	24	
Higher dose compared to standard pain management p	3	3	6	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.641 [85]
Method	Wilcoxon (Mann-Whitney)

Notes:

[85] - purely descriptive

Secondary: Non-opioid medication from OP until U5 [categorized] ITT	
End point title	Non-opioid medication from OP until U5 [categorized] ITT
End point description: OP -- end of surgery U5 -- Dismissal day (not before postop day 6)	
End point type	Secondary
End point timeframe: OP - U5	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	20	31	
Units: [-]				
Not received	0	0	0	
Lower dose compared to standard pain management pr	0	1	1	
Dose according to standard pain management protoco	7	9	16	
Higher dose compared to standard pain management p	4	10	14	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.643 [86]
Method	Wilcoxon (Mann-Whitney)

Notes:

[86] - purely descriptive

Secondary: Weak opioid medication from U5 until U7 [categorized] ITT

End point title	Weak opioid medication from U5 until U7 [categorized] ITT

End point description:

U5 -- Dismissal day (not before postop day 6)
U7 -- 42 days postop

End point type	Secondary

End point timeframe:

U5 -- U7

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	16	27	
Units: [-]				
Not received	4	9	13	
Lower dose compared to standard pain management pr	3	1	4	
Dose according to standard pain management protoco	3	6	9	
Higher dose compared to standard pain management p	1	0	1	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.499 [87]
Method	Wilcoxon (Mann-Whitney)

Notes:

[87] - purely descriptive

Secondary: Strong opioid medication from U5 until U7 [categorized] ITT

End point title	Strong opioid medication from U5 until U7 [categorized] ITT

End point description:

U5 -- Dismissal day (not before postop day 6)
U7 -- 42 days postop

End point type	Secondary
End point timeframe: U5 - U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
Not received	8	11	19	
Lower dose compared to standard pain management pr	0	0	0	
Dose according to standard pain management protoco	1	1	2	
Higher dose compared to standard pain management p	2	3	5	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.999 [88]
Method	Wilcoxon (Mann-Whitney)
Notes: [88] - purely descriptive	

Secondary: Non-opioid medication from U5 until U7 [categorized] ITT

End point title	Non-opioid medication from U5 until U7 [categorized] ITT
End point description: U5 -- Dismissal day (not before postop day 6) U7 -- 42 days postop	
End point type	Secondary
End point timeframe: U5 - U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	16	27	
Units: [-]				
Not received	0	1	1	

Lower dose compared to standard pain management pr	5	5	10	
Dose according to standard pain management protoco	3	7	10	
Higher dose compared to standard pain management p	3	3	6	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.995 [89]
Method	Wilcoxon (Mann-Whitney)

Notes:

[89] - purely descriptive

Secondary: Weak opioid medication from U7 until U8 [categorized] ITT

End point title	Weak opioid medication from U7 until U8 [categorized] ITT
End point description: U7 -- 42 days postop U8 -- 84 days postop	
End point type	Secondary
End point timeframe: U7 - U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
Not received	8	11	19	
Lower dose compared to standard pain management pr	0	0	0	
Dose according to standard pain management protoco	0	0	0	
Higher dose compared to standard pain management p	3	4	7	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.999 [90]
Method	Wilcoxon (Mann-Whitney)

Notes:

[90] - purely descriptive

Secondary: Strong opioid medication from U7 until U8 [categorized] ITT

End point title	Strong opioid medication from U7 until U8 [categorized] ITT

End point description:

U7 -- 42 days postop
U8 -- 84 days postop

End point type	Secondary

End point timeframe:

U7 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	14	25	
Units: [-]				
Not received	8	11	19	
Lower dose compared to standard pain management pr	0	0	0	
Dose according to standard pain management protoco	2	1	3	
Higher dose compared to standard pain management p	1	2	3	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.983 [91]
Method	Wilcoxon (Mann-Whitney)

Notes:

[91] - purely descriptive

Secondary: Non-opioid medication from U7 until U8 [categorized] ITT

End point title	Non-opioid medication from U7 until U8 [categorized] ITT

End point description:

U7 -- 42 days postop
U8 -- 84 days postop

End point type	Secondary
End point timeframe: U7 - U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	16	27	
Units: [-]				
Not received	3	4	7	
Lower dose compared to standard pain management pr	3	3	6	
Dose according to standard pain management protoco	2	7	9	
Higher dose compared to standard pain management p	3	2	5	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.979 [92]
Method	Wilcoxon (Mann-Whitney)

Notes:
[92] - purely descriptive

Secondary: HADS anxiety at U2 [-] PP

End point title	HADS anxiety at U2 [-] PP
End point description: U2 -- 1 day preop	
End point type	Secondary
End point timeframe: U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
median (inter-quartile range (Q1-Q3))	4.00 (2.00 to 8.00)	7.00 (4.00 to 11.00)	7.00 (3.00 to 9.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.23 [93]
Method	Wilcoxon (Mann-Whitney)

Notes:
[93] - purely descriptive

Secondary: HADS anxiety at U7 [-] PP

End point title	HADS anxiety at U7 [-] PP
End point description: U7 -- 42 days postop	
End point type	Secondary
End point timeframe: U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
median (inter-quartile range (Q1-Q3))	3.00 (1.00 to 4.00)	3.00 (0.00 to 7.00)	3.00 (1.00 to 4.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.596 [94]
Method	Wilcoxon (Mann-Whitney)

Notes:
[94] - purely descriptive

Secondary: HADS anxiety at U8 [-] PP	
End point title	HADS anxiety at U8 [-] PP
End point description: U8 -- 84 days postop	
End point type	Secondary
End point timeframe: U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	13	23	
Units: [-]				
median (inter-quartile range (Q1-Q3))	3.00 (2.00 to 6.00)	4.00 (2.00 to 6.00)	3.00 (2.00 to 6.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.683 [95]
Method	Wilcoxon (Mann-Whitney)

Notes:
[95] - purely descriptive

Secondary: HADS depression at U2 [-] PP	
End point title	HADS depression at U2 [-] PP
End point description: U2 -- 1 day preop	
End point type	Secondary
End point timeframe: U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
median (inter-quartile range (Q1-Q3))	5.00 (3.00 to 7.00)	8.00 (4.00 to 11.00)	6.00 (4.00 to 10.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.251 [96]
Method	Wilcoxon (Mann-Whitney)

Notes:
[96] - purely descriptive

Secondary: HADS depression at U7 [-] PP

End point title	HADS depression at U7 [-] PP
End point description: U7 -- 42 days postop	
End point type	Secondary
End point timeframe: U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
median (inter-quartile range (Q1-Q3))	2.00 (2.00 to 3.00)	3.00 (2.00 to 7.00)	3.00 (2.00 to 6.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.254 [97]
Method	Wilcoxon (Mann-Whitney)

Notes:
[97] - purely descriptive

Secondary: HADS depression at U8 [-] PP	
End point title	HADS depression at U8 [-] PP
End point description: U8 -- 84 days postop	
End point type	Secondary
End point timeframe: U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	13	23	
Units: [-]				
median (inter-quartile range (Q1-Q3))	2.50 (1.00 to 6.00)	6.00 (3.00 to 8.00)	4.00 (1.00 to 6.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.174 [98]
Method	Wilcoxon (Mann-Whitney)

Notes:
[98] - purely descriptive

Secondary: SF36 mental sum score at U2 [-] PP	
End point title	SF36 mental sum score at U2 [-] PP
End point description: U2 -- 1 day preop	
End point type	Secondary
End point timeframe: U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
median (inter-quartile range (Q1-Q3))	35.34 (32.39 to 55.46)	43.90 (21.20 to 50.67)	41.38 (31.88 to 50.67)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.721 [99]
Method	Wilcoxon (Mann-Whitney)

Notes:
[99] - purely descriptive

Secondary: SF36 mental sum score at U7 [-] PP

End point title	SF36 mental sum score at U7 [-] PP
End point description: U7 -- 42 days postop	
End point type	Secondary
End point timeframe: U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
median (inter-quartile range (Q1-Q3))	47.20 (40.99 to 60.81)	46.28 (31.02 to 52.45)	46.74 (37.86 to 52.49)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.259 [100]
Method	Wilcoxon (Mann-Whitney)

Notes:
[100] - purely descriptive

Secondary: SF36 mental sum score at U8 [-] PP	
End point title	SF36 mental sum score at U8 [-] PP
End point description: U8 -- 84 days postop	
End point type	Secondary
End point timeframe: U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	13	23	
Units: [-]				
median (inter-quartile range (Q1-Q3))	47.26 (42.72 to 57.86)	50.86 (27.77 to 53.58)	50.39 (30.37 to 57.01)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.648 [101]
Method	Wilcoxon (Mann-Whitney)

Notes:
[101] - purely descriptive

Secondary: SF36 physical sum score at U2 [-] PP	
End point title	SF36 physical sum score at U2 [-] PP
End point description: U2 -- 1 day preop	
End point type	Secondary
End point timeframe: U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
median (inter-quartile range (Q1-Q3))	24.70 (20.19 to 33.42)	31.08 (27.83 to 37.22)	30.74 (23.00 to 34.26)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.097 [102]
Method	Wilcoxon (Mann-Whitney)

Notes:
[102] - purely descriptive

Secondary: SF36 physical sum score at U7 [-] PP

End point title	SF36 physical sum score at U7 [-] PP
End point description: U7 -- 42 days postop	
End point type	Secondary
End point timeframe: U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
median (inter-quartile range (Q1-Q3))	31.43 (26.30 to 36.55)	40.21 (35.41 to 41.52)	36.34 (29.24 to 41.32)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.061 [103]
Method	Wilcoxon (Mann-Whitney)

Notes:
[103] - purely descriptive

Secondary: SF36 physical sum score at U8 [-] PP	
End point title	SF36 physical sum score at U8 [-] PP
End point description: U8 -- 84 days postop	
End point type	Secondary
End point timeframe: U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	13	23	
Units: [-]				
median (inter-quartile range (Q1-Q3))	34.98 (28.17 to 47.15)	38.61 (27.88 to 43.56)	37.56 (27.88 to 47.08)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.648 [104]
Method	Wilcoxon (Mann-Whitney)

Notes:
[104] - purely descriptive

Secondary: Oswestry Disability Questionnaire Low Back Pain at U2 [%] PP	
End point title	Oswestry Disability Questionnaire Low Back Pain at U2 [%] PP
End point description: U2 -- 1 day preop	
End point type	Secondary
End point timeframe: U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [%]				
median (inter-quartile range (Q1-Q3))	42.00 (36.00 to 55.56)	43.33 (32.00 to 48.00)	42.67 (35.56 to 50.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Nabilone (V-Gruppe) v Placebo (K-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.809 [105]
Method	Wilcoxon (Mann-Whitney)

Notes:

[105] - purely descriptive

Secondary: Oswestry Disability Questionnaire Low Back Pain at U7 [%] PP	
End point title	Oswestry Disability Questionnaire Low Back Pain at U7 [%] PP
End point description: U7 -- 42 days postop	
End point type	Secondary
End point timeframe: U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [%]				
median (inter-quartile range (Q1-Q3))	26.67 (20.00 to 44.44)	34.00 (22.22 to 40.00)	33.67 (22.22 to 40.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.808 [106]
Method	Wilcoxon (Mann-Whitney)

Notes:

[106] - purely descriptive

Secondary: Oswestry Disability Questionnaire Low Back Pain at U8 [%] PP	
End point title	Oswestry Disability Questionnaire Low Back Pain at U8 [%] PP
End point description: U8 -- 84 days postop	
End point type	Secondary
End point timeframe: U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	13	23	
Units: [%]				
median (inter-quartile range (Q1-Q3))	26.25 (12.00 to 44.00)	33.33 (24.44 to 42.22)	32.00 (15.56 to 44.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.367 [107]
Method	Wilcoxon (Mann-Whitney)

Notes:
[107] - purely descriptive

Secondary: Pinprick pain threshold at U2 [mN] PP	
End point title	Pinprick pain threshold at U2 [mN] PP
End point description: U2 -- 1 day preop	
End point type	Secondary
End point timeframe: U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	13	23	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	194.01 (111.43 to 294.07)	194.01 (128.00 to 256.00)	194.01 (111.43 to 256.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.748 [108]
Method	Wilcoxon (Mann-Whitney)

Notes:
[108] - purely descriptive

Secondary: Pinprick pain threshold at U3 [mN] PP

End point title	Pinprick pain threshold at U3 [mN] PP
End point description: U3 -- 2 days postop	
End point type	Secondary
End point timeframe: U3	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	14	25	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	147.03 (97.01 to 168.90)	181.45 (128.00 to 256.00)	147.03 (97.01 to 222.86)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.349 [109]
Method	Wilcoxon (Mann-Whitney)

Notes:
[109] - purely descriptive

Secondary: Pinprick pain threshold at U4 [mN] PP

End point title	Pinprick pain threshold at U4 [mN] PP
End point description: U4 -- 5 days postop	
End point type	Secondary
End point timeframe: U4	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	14	25	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	111.43 (97.01 to 194.01)	168.90 (97.01 to 194.01)	128.00 (97.01 to 194.01)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.617 [110]
Method	Wilcoxon (Mann-Whitney)

Notes:
[110] - purely descriptive

Secondary: Pinprick pain threshold at U5 [mN] PP

End point title	Pinprick pain threshold at U5 [mN] PP
End point description: U5 -- Dismissal day (not before postop day 6)	
End point type	Secondary
End point timeframe: U5	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	168.90 (84.45 to 256.00)	194.01 (111.43 to 256.00)	181.45 (111.43 to 256.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.807 [111]
Method	Wilcoxon (Mann-Whitney)

Notes:
[111] - purely descriptive

Secondary: Pinprick pain threshold at U7 [mN] PP

End point title	Pinprick pain threshold at U7 [mN] PP
End point description: U7 -- 42 days postop	
End point type	Secondary
End point timeframe: U7	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	9	12	21	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	194.01 (168.90 to 222.86)	170.52 (111.43 to 256.00)	194.01 (128.00 to 256.00)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.517 [112]
Method	Wilcoxon (Mann-Whitney)

Notes:
[112] - purely descriptive

Secondary: Pinprick pain threshold at U8 [mN] PP

End point title	Pinprick pain threshold at U8 [mN] PP
End point description: U8 -- 84 days postop	
End point type	Secondary
End point timeframe: U8	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	10	17	
Units: [mN]				
median (inter-quartile range (Q1-Q3))	222.86 (97.01 to 294.07)	258.46 (147.03 to 294.07)	222.86 (128.00 to 294.07)	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	17
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.544 [113]
Method	Wilcoxon (Mann-Whitney)

Notes:
[113] - purely descriptive

Secondary: Weak opioid medication from U1 until U2 [categorized] PP

End point title	Weak opioid medication from U1 until U2 [categorized] PP
End point description: U1 -- Baseline U2 -- 1 day preop	
End point type	Secondary
End point timeframe: U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
Not received	9	11	20	
Lower dose compared to standard pain management pr	0	2	2	
Dose according to standard pain management protoco	1	1	2	
Higher dose compared to standard pain management p	1	1	2	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.88 [114]
Method	Wilcoxon (Mann-Whitney)

Notes:

[114] - purely descriptive

Secondary: Strong opioid medication from U1 until U2 [categorized] PP

End point title	Strong opioid medication from U1 until U2 [categorized] PP
End point description:	
U1 -- Baseline U2 -- 1 day preop	
End point type	Secondary
End point timeframe:	
U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
Not received	8	13	21	
Lower dose compared to standard pain management pr	0	0	0	
Dose according to standard pain management protoco	2	1	3	

Higher dose compared to standard pain management p	1	1	2	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.593 [115]
Method	Wilcoxon (Mann-Whitney)

Notes:

[115] - purely descriptive

Secondary: Non-opioid medication from U1 until U2 [categorized] PP	
End point title	Non-opioid medication from U1 until U2 [categorized] PP
End point description: U1 -- Baseline U2 -- 1 day preop	
End point type	Secondary
End point timeframe: U1 - U2	

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
Not received	5	11	16	
Lower dose compared to standard pain management pr	5	2	7	
Dose according to standard pain management protoco	1	2	3	
Higher dose compared to standard pain management p	0	0	0	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.282 [116]
Method	Wilcoxon (Mann-Whitney)

Notes:

[116] - purely descriptive

Secondary: Weak opioid medication from U5 until U7 [categorized] PP

End point title	Weak opioid medication from U5 until U7 [categorized] PP

End point description:

U5 -- Dismissal day (not before postop day 6)
U7 -- 42 days postop

End point type	Secondary

End point timeframe:

U5 - U7

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
Not received	4	8	12	
Lower dose compared to standard pain management pr	3	1	4	
Dose according to standard pain management protoco	3	6	9	
Higher dose compared to standard pain management p	1	0	1	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.608 [117]
Method	Wilcoxon (Mann-Whitney)

Notes:

[117] - purely descriptive

Secondary: Strong opioid medication from U5 until U7 [categorized] PP

End point title	Strong opioid medication from U5 until U7 [categorized] PP

End point description:

U5 -- Dismissal day (not before postop day 6)
U7 -- 42 days postop

End point type	Secondary

End point timeframe:

U5 - U7

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	14	25	
Units: [-]				
Not received	8	11	19	
Lower dose compared to standard pain management pr	0	0	0	
Dose according to standard pain management protoco	1	1	2	
Higher dose compared to standard pain management p	2	2	4	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.932 [118]
Method	Wilcoxon (Mann-Whitney)

Notes:

[118] - purely descriptive

Secondary: Non-opioid medication from U5 until U7 [categorized] PP

End point title	Non-opioid medication from U5 until U7 [categorized] PP

End point description:

U5 -- Dismissal day (not before postop day 6)
U7 -- 42 days postop

End point type	Secondary

End point timeframe:

U5 - U7

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
Not received	0	1	1	
Lower dose compared to standard pain management pr	5	4	9	
Dose according to standard pain management protoco	3	7	10	
Higher dose compared to standard pain management p	3	3	6	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.938 [119]
Method	Wilcoxon (Mann-Whitney)

Notes:

[119] - purely descriptive

Secondary: Weak opioid medication from U7 until U8 [categorized] PP

End point title	Weak opioid medication from U7 until U8 [categorized] PP

End point description:

U7 -- 42 days postop
U8 -- 84 days postop

End point type	Secondary

End point timeframe:

U7 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	14	25	
Units: [-]				
Not received	8	10	18	
Lower dose compared to standard pain management pr	0	0	0	
Dose according to standard pain management protoco	0	0	0	
Higher dose compared to standard pain management p	3	4	7	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Nabilone (V-Gruppe) v Placebo (K-Gruppe)
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.999 [120]
Method	Wilcoxon (Mann-Whitney)

Notes:

[120] - purely descriptive

Secondary: Strong opioid medication from U7 until U8 [categorized] PP

End point title	Strong opioid medication from U7 until U8 [categorized] PP

End point description:

U7 -- 42 days postop
U8 -- 84 days postop

End point type	Secondary

End point timeframe:

U7 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	13	24	
Units: [-]				
Not received	8	11	19	
Lower dose compared to standard pain management pr	0	0	0	
Dose according to standard pain management protoco	2	1	3	
Higher dose compared to standard pain management p	1	1	2	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)

Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6 [121]
Method	Wilcoxon (Mann-Whitney)

Notes:

[121] - purely descriptive

Secondary: Non-opioid medication from U7 until U8 [categorized] PP

End point title	Non-opioid medication from U7 until U8 [categorized] PP

End point description:

U7 -- 42 days postop
U8 -- 84 days postop

End point type	Secondary

End point timeframe:

U7 - U8

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
Not received	3	4	7	
Lower dose compared to standard pain management pr	3	2	5	
Dose according to standard pain management protoco	2	7	9	
Higher dose compared to standard pain management p	3	2	5	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.999 [122]
Method	Wilcoxon (Mann-Whitney)

Notes:

[122] - purely descriptive

Secondary: Weak opioid medication from OP until U5 [categorized] PP

End point title	Weak opioid medication from OP until U5 [categorized] PP

End point description:

OP -- end of surgery

U5 -- Dismissal day (not before postop day 6)

End point type	Secondary

End point timeframe:

OP - U5

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
Not received	4	1	5	
Lower dose compared to standard pain management pr	0	6	6	
Dose according to standard pain management protoco	6	8	14	
Higher dose compared to standard pain management p	1	0	1	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.999 [123]
Method	Wilcoxon (Mann-Whitney)

Notes:

[123] - purely descriptive

Secondary: Strong opioid medication from OP until U5 [categorized] PP

End point title	Strong opioid medication from OP until U5 [categorized] PP

End point description:

OP – end of surgery
U5 -- Dismissal day (not before postop day 6)

End point type	Secondary

End point timeframe:

OP - U5

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	14	25	
Units: [-]				
Not received	0	0	0	
Lower dose compared to standard pain management pr	0	0	0	
Dose according to standard pain management protoco	8	12	20	
Higher dose compared to standard pain management p	3	2	5	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.623 [124]
Method	Wilcoxon (Mann-Whitney)

Notes:

[124] - purely descriptive

Secondary: Non-opioid medication from OP until U5 [categorized] PP

End point title	Non-opioid medication from OP until U5 [categorized] PP

End point description:

OP – end of surgery
U5 -- Dismissal day (not before postop day 6)

End point type	Secondary

End point timeframe:

OP - U5

End point values	Placebo (K-Gruppe)	Nabilone (V-Gruppe)	PP	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	11	15	26	
Units: [-]				
Not received	0	0	0	
Lower dose compared to standard pain management pr	0	1	1	
Dose according to standard pain management protoco	7	6	13	
Higher dose compared to standard pain management p	4	8	12	

Statistical analyses

Statistical analysis title	Group comparison
Comparison groups	Placebo (K-Gruppe) v Nabilone (V-Gruppe)
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.607 [125]
Method	Wilcoxon (Mann-Whitney)

Notes:

[125] - purely descriptive

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Safety and tolerability assessments were performed for every subject from baseline examination (U1) until last visit (U8).

Assessment type	Non-systematic

Dictionary used

Dictionary name	clin. usual terms
Dictionary version	1

Reporting groups

Reporting group title	Verum
Reporting group description: -	
Reporting group title	Placebo

Reporting group description: -

Serious adverse events	Verum	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 24 (25.00%)	1 / 12 (8.33%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Surgical and medical procedures			
Dural tear	Additional description: Dural leak and CSF fistula		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain	Additional description: postoperative, surgical site		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Postoperative delirium			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Wound infection			

subjects affected / exposed	4 / 24 (16.67%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Verum	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 24 (75.00%)	7 / 12 (58.33%)	
Cardiac disorders			
Tachycardia	Additional description: during break from digitalis medication		
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
Hypertension	Additional description: preexisting hypertension		
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
Surgical and medical procedures			
Anaemia	Additional description: blood loss during surgery		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	1	
Dural tear			
subjects affected / exposed	3 / 24 (12.50%)	1 / 12 (8.33%)	
occurrences (all)	4	4	
Epidural haemorrhage	Additional description: postoperative haematoma		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	1	
Nervous system disorders			
Sciatica			
subjects affected / exposed	5 / 24 (20.83%)	0 / 12 (0.00%)	
occurrences (all)	5	5	
Tremor			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
Fatigue			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	1	

Vertigo positional			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	1	
Vertigo			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
General disorders and administration site conditions			
Discomfort	Additional description: General discomfort		
subjects affected / exposed	0 / 24 (0.00%)	2 / 12 (16.67%)	
occurrences (all)	2	2	
Immune system disorders			
Influenza			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	1	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	4 / 24 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	4	4	
Intestinal pain			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	1	
Flatulence			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	1	
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	1	
Skin and subcutaneous tissue disorders			
Wound dehiscence	Additional description: preexisting rheumatoid arthritis and biological medication		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	1	
Rash			

subjects affected / exposed	3 / 24 (12.50%)	0 / 12 (0.00%)	
occurrences (all)	3	3	
Swelling	Additional description: of Hands		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	1	
Psychiatric disorders			
Nightmare			
subjects affected / exposed	3 / 24 (12.50%)	2 / 12 (16.67%)	
occurrences (all)	5	5	
Renal and urinary disorders			
Urinary retention postoperative			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	1	
Infections and infestations			
Bacteriuria			
subjects affected / exposed	2 / 24 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	2	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported