Supplementary Material

This material has been provided by the authors to give readers additional information about their work.

VER-01 Shows Enhanced Gastrointestinal Tolerability, Superior Pain Relief, and Improved Sleep Quality Compared to Opioids in Treating Chronic Low Back Pain: A Randomized Phase 3 Clinical Trial

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Content

1 Eligibility criteria

Inclusion Criteria

Patients must meet all of the following inclusion criteria in order to be eligible to participate in the study.

1. Male and female patients ≥18 years of age
2. Provision of informed consent form voluntarily signed and dated by the patient
3. For women of childbearing potential and men of reproductive potential: use of a reliable contraceptive method (Pearl index < 1) at least 1 month before the start of the study and willingness to use it during the study participation and 3 months after the last intake of the test or comparative intervention
4. Patient understands the local language and is willing and able to comply with scheduled visits, treatment plan, patient diary and other study related procedures throughout study participation
5. Chronic (for at least 3 months) non-specific pain in the lower back (between the 12th thoracic vertebra and lower gluteal folds). Non-specific pain refers to pain without clear indication of a specific treatable cause.
6. Patients with indicated drug treatment* where previous optimized treatments** with non-opioid analgesics (including combinations) have not led to sufficient pain relief or were unsuitable due to contraindications or intolerance.

   ** Drug treatment is indicated if analgesic drug therapy is considered supportive for the realization of activating measures, or if the patient has unbearable functional disabilities as a result of the pain, despite regularly performing these measures.*

   *** Treatment is considered optimized when a further increased drug dose is unsuitable from a medical perspective considering side effects and/or it is not expected that a higher drug dose would result in a further advantage in terms of efficacy.*

7. Low back pain intensity on average at least 4 points on an 11-point Numeric Rating Scale in the last 4 weeks prior screening visit 1 (V1)
8. Ongoing non-drug pain therapy (physical or behavioral therapy) must have been stable for at least 2 weeks prior V1 and must be continued during the run-in phase
9. Ongoing additional analgesic treatment prior V1 must be continued during the Run-in Phase
10. Bowel Function Index total score of 28.8 or less at V1

Exclusion Criteria

Patients who meet any of the following exclusion criteria will be excluded from participation in this study.

1. Patients with a known history of alcohol/drug/medication abuse or dependency and previous or current use of methadone (Nicotine abuse or dependency are not relevant for assessment of patient's eligibility)
2. Evidence of drugs of abuse or illegal drugs by urine drug test performed at V1 (Drugs tested at V1 are: THC, cocaine, morphine, methamphetamine, amphetamine, methadone, benzodiazepine and ecstasy)
3. Known intolerance or hypersensitivity to ingredients of rescue medication, opioid therapy (assigned by the Investigator) and/or VER-01
4. Participation in another clinical interventional study within the last 30 days prior V1
5. Occupational groups with primary activity of operating machinery and driving motor vehicles
6. Planned blood donation or planned donation or freezing of sperm or oocytes during study participation and 3 months after end of study participation
7. Pregnant or breastfeeding female patients
8. Patient is unable to provide written informed consent, in need for care, has a guardian/caretaker, is immobile, or is particularly vulnerable (e.g., imprisoned; institutionalised by a court or judicial authority; dependent or employed by the sponsor, an external service provider of the sponsor (involved in the conduct of the study), the Investigator or the trial site)
9. Known use of opioid or cannabis-based treatments within 30 days before V1
10. Patients for whom cannabis or opioid therapy is not indicated, e.g., due to a history of non-response to opioid therapy or cannabis-based medicines in the treatment of chronic non-specific low back pain in the past.
11. Start of or planned non-drug pain therapy during run-in phase (physical or behavioral therapy)
12. Start of or planned start of an additional analgesic treatment during run-in phase (This does not include rescue medication, which can be taken during the run-in phase.)
13. Ongoing monoamine oxidase inhibitor therapy at V1
14. Patients with history of cancer in the last 5 years prior to V1. Except for cutaneous basal cell or squamous cell cancer resolved by excision without recurrence and cervical cancer in situ resolved by excision with negative pap test.
15. Painful comorbidities which could interfere with the low back pain intensity assessment during the study

16. Known history of human immunodeficiency virus (HIV) infection
17. Severe forms of the following diseases: haematological / autoimmune / endocrine / renal / hepatic / respiratory / cardiovascular / neurological / gastrointestinal / symptomatic peripheral vascular diseases.

Examples (not fully exhaustive) for severe forms of the following diseases are listed below:

- Haematological: Anaemia, severe bleeding disorder
- Autoimmune: Severe forms of systemic lupus erythematosus, severe forms of type I diabetes
- Endocrine: Severe forms of metabolic bone disease
- Renal: Severe stages of chronic kidney disease
- Hepatic: Severe hepatic insufficiency
- Respiratory: Severe bronchial asthma, hypercapnia/respiratory failure

2 Demographics and baseline characteristics

Table S1. Demographics and baseline characteristics – all treated patients[1]		
Characteristic	**VER-01 (N=189)**	**Opioids (N=186)**
Age [years], mean (SD)	53.9 (13.6)	55.7 (12.9)
Female sex, n (%)	118 (62.4)	113 (60.8)
BMI at baseline [kg/m^2], mean (SD)	29.19 (5.67)	29.66 (6.27)
PainDETECT baseline score, mean (SD)	14.7 (7.8)	14.2 (8.2)
PainDETECT baseline score >18, n (%)	60 (31.7)	61 (32.8)
NRS pain score, mean (SD)	6.6 (1.3)	6.6 (1.4)
NRS sleep score, mean (SD)	5.5 (2.0)	5.3 (2.2)

Abbreviations: BMI = Body Mass Index; NRS= Numeric Rating Scale; SD = Standard Deviation

Table S2. Demographics and baseline characteristics – neuropathic pain cohort (PainDETECT > 18)[2]		
Characteristic	**VER-01 (N=60)**	**Placebo (N=61)**
Age [years], mean (SD)	54.4 (15.1)	56.0 (12.8)
Female sex, n (%)	38 (63.3)	40 (65.6)
BMI at baseline [kg/m^2], mean (SD)	28.52 (5.80)	30.26 (6.72)
PainDETECT baseline score, mean (SD)	24.0 (3.2)	23.9 (3.6)
PainDETECT baseline score >18, n (%)	60 (100.0)	61 (100.0)
Severe Pain (NRS≥ 7) at baseline, n (%)	28 (46.7)	26 (42.6)
NRS pain score, mean (SD)	7.0 (1.3)	6.8 (1.4)
NRS sleep score, mean (SD)	6.3 (1.4)	5.7 (1.9)

Table S3. Demographics and other baseline characteristics – severe pain cohort (NRS pain ≥ 7)[3]		
Characteristic	**VER-01 (N=80)**	**Placebo (N=80)**
Age [years], mean (SD)	56.4 (12.8)	56.3 (12.9)
Female sex, n (%)	52 (65.0)	59 (73.8)
BMI at baseline [kg/m^2], mean (SD)	29.29 (5.37)	29.01 (6.07)
PainDETECT baseline score, mean (SD)	15.3 (7.8)	14.2 (8.1)
PainDETECT baseline score >18, n (%)	28 (35.0)	26 (32.5)
Severe Pain (NRS≥ 7) at baseline, n (%)	80 (100.0)	80 (100.0)
NRS pain score, mean (SD)	7.8 (0.8)	7.9 (0.7)
NRS sleep score, mean (SD)	6.8 (1.7)	6.6 (1.9)

[2] BMI = Body Mass Index; NRS= Numeric Rating Scale; SD = Standard Deviation

[3] Abbreviations: BMI = Body Mass Index; NRS= Numeric Rating Scale; SD = Standard Deviation

3 Primary tolerability estimand

Table S4. Primary tolerability endpoint with sensitivities

Primary Estimand

Covariable (Effect vs. Reference)	**Effect estimate[a]**	**Standard error[a]**	**p[a]**	**Estimate**	**95% CI**
Treatment group (VER-01 vs. opioids)	-1.38	0.51	0.007	0.25	[0.09:0.69]
Neuropathic pain component (neuropathic vs. nociceptive)	-0.60	0.49	0.214		
Age group (≥65 vs. <65 years)	-0.09	0.44	0.832		
Sex (female vs. male)	-0.20	0.38	0.601		

Sensitivity analysis for primary estimand, based on "Jump-to-Reference" Model

Covariable	**Effect estimate[b]**	**Standard error[b]**	**p[b]**	**Estimate**	**95% CI**
Treatment group	-1.26	0.49	0.009	0.28	[0.11:0.73]
Neuropathic pain component	-0.51	0.47	0.275		
Age group (≥65 vs. <65 years)	-0.09	0.44	0.842		
Sex (female vs. male)	-0.17	0.38	0.647		

Sensitivity analysis for primary estimand, based on "Last observation carried forward"

Covariable	**Effect estimate[c]**	**Standard error[c]**	**p[c]**	**Estimate**	**95% CI**
Treatment group	-1.68	0.54	0.002	0.19	[0.06:0.54]
Neuropathic pain component	-0.64	0.49	0.188		
Age group (≥65 vs. <65 years)	-0.13	0.44	0.759		
Sex (female vs. male)	-0.34	0.38	0.370		
Treatment group					

Sensitivity analysis for primary estimand, "Tipping point analysis on the relative risk for constipation occurrence at Visit 9"

Shift	**Covariate**	**Effect estimate[d]**	**Standard error[d]**	**p[d]**	**Estimate**	**95% CI**

Shift prior to tipping point	Treatment group	-1.28	0.50	0.011	0.28	[0.10:0.74]
Shift for tipping point	Treatment group	-1.15	0.49	0.012	0.32	[0.12:0.82]
Tipping point: 2 points						

[a] Parameter estimates, corresponding standard errors and p-values are based on a modified poisson model with binary target variable 'occurrence of constipation' and treatment group as main effect as well as baseline characteristics neuropathic pain component, age group and sex as covariables based on imputed data using MAR assumption. Presented results are combined results for multiply imputed data using Rubin's rule.

[b]Parameter estimates, corresponding standard errors and p-values are based on a modified poisson model with binary target variable 'occurrence of constipation' and treatment group as main effect as well as baseline characteristics neuropathic pain component, age group and sex as covariables based on imputed data using MNAR (Jump-to reference) assumption. Presented results are combined results for multiply imputed data using Rubin's rule.

[c] Parameter estimates, corresponding standard errors and p-values are based on a modified poisson model with binary target variable 'occurrence of constipation' and treatment group as main effect as well as baseline characteristics neuropathic pain component, age group and sex as covariables based on imputed data using LOCF (last observation carried forward) assumption

[d] Parameter estimates on the log-scale, corresponding standard errors and p-values are based on a modified poisson model with binary target variable 'occurrence of constipation' and treatment group as main effect as well as baseline characteristics neuropathic pain component, age group and sex as covariables based on imputed data using tipping point; presented results are combined results for multiply imputed data using Rubin's rule.

4 Secondary tolerability endpoints

Table S5. Secondary tolerability endpoints[4]

Endpoint	**VER-01 (N=189)**	**Opioids (N=186)**	**MD (SE) / RR** VER-01 vs. opioids [95% CI]
Number and percentage of subjects with treatment-emergent constipation at V6, n (%)	5 (3.0)	18 (11.6)	0.26 [0.10:0.69]
Number and percentage of subjects with treatment-emergent constipation at V9, n (%)	3 (1.9)	19 (12.8)	0.15 [0.05:0.50]
CFB in BFI total score at V6, LS mean (SE) [95% CI]	1.13 (0.95) [-0.74:3.00]	5.17 (0.98) [3.23:7.10]	-4.04 (1.35) [-6.69:-1.38]

[4] Abbreviations: BFI = Bowel Function Index; CFB= Change from Baseline; CI = Confidence Interval; LS mean = Least Squares Mean; MD = Mean Difference; RR = Relative Risk; SE = Standard Error; SMWQ = Study Medication Withdrawal Questionnaire; TEAE = Treatment Emergent Adverse Event

CFB in BFI total score at V9, LS mean (SE) [95% CI]	0.27 (1.09) [-1.87:2.40]	6.60 (1.12) [4.40:8.81]	-6.34 (1.54) [-9.38:-3.30]
CFB in BFI "ease of defecation" score at V6, LS mean (SE) [95% CI]	1.34 (1.11) [-0.85:3.54]	5.20 (1.15) [2.93:7.46]	-3.85 (1.58) [-6.97:- 0.74]
CFB in BFI "ease of defecation" score at V9, LS mean (SE) [95% CI]	-0.2 (1.18) [-2.52:2.11]	6.48 (1.67) [4.09:8.87]	-6.68 (1.67) [-9.98:-3.39]
CFB in BFI "feeling of incomplete bowel evacuation" score at V6, LS mean (SE) [95% CI]	0.78 (0.99) [-1.17:2.74]	4.53 (1.03) [2.51:6.55]	-3.75 (1.41) [-6.52:-0.97]
CFB in BFI "feeling of incomplete bowel evacuation" score at V9, LS mean (SE) [95% CI]	-0.01 (1.14) [-2.26:2.24]	6.27 (1.18) [3.94:8.59]	-6.27 (1.63) [-9.48:-3.07]
CFB in BFI "personal judgement of defecation" score at V6, LS mean (SE) [95% CI]	0.87 (1.01) [-1.11:2.86]	5.82 (1.04) [3.77:7.88]	-4.95 (1.43) [-7.77:-2.13]
CFB in BFI "personal judgement of defecation" score at V9, LS mean (SE) [95% CI]	0.50 (1.23) [-1.92:2.91]	7.23 (1.27) [4.73:9.72]	-6.73 (1.74) [-10.16:-3.30]
Number and percentage of patients with TEAEs, n (%)	138 (73)	137 (74)	-
Number of patients with intake of laxatives from V2 to V9, Pat n (Pat %)	11 (5.8)	32 (17.2)	-
Number of days with intake of laxatives between V2 and V9, Mean (SD)	57.2 (84.2)	49.2 (63.3)	-
SMWQ total score at V10, mean (SD)	7.1 (6.2)	7.9 (6.7)	-0.7 (0.78) [-2.3:0.8]
SMWQ total score at Follow-Up visit, mean (SD)	9.2 (6.2)	8.4 (4.9)	0.8 (1.50) [-2.2:3.8]

5 Secondary efficacy endpoints

Table S6. Key secondary efficacy endpoints

Endpoint	Estimate	p	95% CI

Common risk difference in 30% pain responders at week 27	0.44	0.430	[-0.07:0.15]
Common risk difference in 30% pain responders at week 27 – patients with painDETECT score > 18	0.01	0.895	[-0.18:0.21]
Common risk differences in 30% improvement of the mean daily low back pain interference with sleep score at week 27	0.05	0.382	[-0.06:0.15]

Table S7. Longitudinal efficacy endpoints

Endpoint	**VER-01** LS mean [95% CI]	**Opioids** LS mean [95% CI]	**MD (SE) / RR** VER-01 vs. opioids [95% CI]
CFB in mean NRS pain intensity throughout wk 15	-2.33 [-2.58:-2.09]	-1.89 [-2.14:-1.64]	-0.44 (0.17) [-0.78:-0.10]
CFB in mean NRS pain intensity throughout wk 27	-2.50 [-2.74:-2.26]	-2.16 [-2.41:-1.92]	-0.34 (0.17) [-0.67:-0.00]
CFB in mean NRS sleep interference throughout wk 15	-2.40 [-2.65:-2.15]	-1.87 [-2.12:-1.61]	-0.53 (0.18) [-0.88:-0.18]
CFB in mean NRS sleep interference throughout wk 27	-2.52 [-2.77:-2.28]	-2.07 [-2.32:-1.82]	-0.45 (0.17) [-0.79:-0.11]
CFB in mean NRS pain intensity throughout wk 15 – patients with painDETECT score > 18	-2.48 [-2.92:-2.03]	-1.90 [-2.34:-1.46]	-0.57 (0.32) [-1.20:0.05]
CFB in mean NRS pain intensity throughout wk 27 - patients with painDETECT score > 18	-2.77 [-3.20:-2.34]	-2.19 [-2.62:-1.76]	-0.57 (0.31) [-1.18:0.04]
CFB in mean NRS sleep interference throughout wk 15 - patients with painDETECT score > 18	-2.79 [-3.26:-2.32]	-1.97 [-2.44:-1.5]	-0.82 (0.34) [-1.49:-0.15]
CFB in mean NRS sleep interference throughout wk 27 - patients with painDETECT score > 18	-3.01 [-3.46:-2.56]	-2.16 [-2.62:-1.71]	-0.84 (0.33) [-1.49:-0.20]

CFB in mean NRS pain intensity throughout wk 15 – subjects with severe pain (NRS≥7)	-2.81 [-3.23:-2.39]	-2.11 [-2.53:-1.69]	-0.70 (0.29) [-1.28:-0.12]
CFB in mean NRS pain intensity throughout wk 27 – subjects with severe pain (NRS≥7)	-3.01 [-3.42:-2.59]	-2.43 [-2.84:-2.01]	-0.58 (0.29) [-1.15:-0.01]
CFB in mean NRS sleep interference throughout wk 15 – subjects with severe pain (NRS≥7)	-2.99 [-3.44:-2.54]	-2.23 [-2.69:-1.77]	-0.76 (0.32) [-1.38:-0.13]
CFB in mean NRS sleep interference throughout wk 27 – subjects with severe pain (NRS≥7)	-3.12 [-3.56:-2.68]	-2.46 [-2.91:-2.02]	-0.66 (0.31) [-1.27:-0.05]
Probability of 30% pain response throughout wk 27	0.58 [0.52:0.64]	0.49 [0.44:0.56]	1.16 [0.99:1.37]
Probability of 50% pain response throughout wk 27	0.34 [0.29:0.41]	0.29 [0.24:0.35]	1.19 [0.92:1.54]
Probability of 30% sleep response throughout wk 27	0.66 [0.60:0.72]	0.58 [0.52:0.65]	1.13 [0.99:1.30]
Probability of 50% sleep response throughout wk 27	0.46 [0.40:0.53]	0.39 [0.33:0.45]	1.19 [0.97:1.46]
Probability of 30% pain response throughout wk 27 - patients with painDETECT score > 18	0.56 [0.46:0.68]	0.53 [0.44:0.65]	1.04 [0.79:1.37]
Probability of 50% pain response throughout wk 27 - patients with painDETECT score > 18	0.36 [0.27:0.48]	0.30 [0.22:0.41]	1.20 [0.78:1.84]
Probability of 30% sleep response throughout wk 27 - patients with painDETECT score > 18	0.68 [0.59:0.79]	0.57 [0.47:0.68]	1.20 [0.95:1.53]
Probability of 50% sleep response throughout wk 27 - patients with painDETECT score > 18	0.48 [0.39:0.72]	0.39 [0.30:0.52]	1.23 [0.86:1.75]
Probability of 30% pain response throughout wk 27 – subjects with severe pain (NRS≥7)	0.57 [0.48:0.67]	0.46 [0.37:0.75]	1.23 [0.95:1.60]
Probability of 50% pain response throughout wk 27 – subjects with severe pain (NRS≥7)	0.33 [0.25:0.43]	0.23 [0.16:0.33]	1.40 [0.91:2.17]

Probability of 30% sleep response throughout wk 27 – subjects with severe pain (NRS≥7)	0.67 [0.58:0.77]	0.57 [0.48:0.67]	1.17 [0.95:1.46]
Probability of 50% sleep response throughout wk 27 – subjects with severe pain (NRS≥7)	0.48 [0.39:0.61]	0.39 [0.30:0.52]	1.23 [0.86:1.75]

Table S8. Other secondary efficacy endpoints[5]	**VER-01 (n=189)**	**Opioids (n=186)**	**MD (SE) / RR** VER-01 vs. opioids [95% CI]
Number and percentage of 30% pain responders at wk 15, n (%)	84 (56.4)	72 (51.1)	1.10 [0.89:1.37]
Number and percentage of 30% pain responders at wk 15 - patients with painDETECT score > 18, n (%)	26 (56.5)	25 (56.8)	0.99 [0.69:1.43]
Number and percentage of 30% sleep responders at wk 15, n (%)	100 (66.7)	88 (63.3)	1.05 [0.89:1.25]
Number and percentage of 30% sleep responders at wk 27, n (%)	104 (74.8)	84 (71.8)	1.04 [0.90:1.21]
Number and percentage of 50% pain responders at wk 15, n (%)	59 (39.6)	47 (33.3)	1.19 [0.87:1.61]
Number and percentage of 50% pain responders at wk 27, n (%)	56 (40.3)	47 (39.5)	1.02 [0.76:1.38]
Number and percentage of 50% pain responders at wk 15 - patients with painDETECT score > 18, n (%)	24 (52.2)	18 (40.9)	1.28 [0.81:2.00]
Number and percentage of 50% pain responders at wk 27 - patients with painDETECT score > 18, n (%)	20 (44.4)	18 (47.4)	0.94 [0.59:1.50]
Number and percentage of 50% sleep responders at wk 15	78 (52.0)	59 (42.4)	1.23 [0.96:1.57]

[5] Abbreviations: BFI = Bowel Function Index; BMI = Body Mass Index; CFB = Change from Baseline; MD = Mean Difference; NRS= Numeric Rating Scale; PGIC= Patient Global Impression of Change; RMDQ = Roland Morris Disability Questionnaire; RR = Relative Risk; SD = Standard Deviation; SE = Standard Error; SF-12= Short-Form Health Survey 12; SMWQ = Study Medication Withdrawal Questionnaire; TEAE = Treatment Emergent Adverse Event; wk = Study Week

Number and percentage of 50% sleep responders at wk 27	67 (48.2)	61 (52.1)	0.92 [0.72:1.18]
CFB at wk 15 in mean NRS pain, Mean (SD)	-2.50 (2.00)	-2.26 (2.18)	-0.25 (0.25) [-0.73:0.24]
CFB at wk 27 in mean NRS pain, Mean (SD)	-2.68 (1.96)	-2.73 (2.12)	0.04 (0.25) [-0.46:0.54]
CFB at wk 15 in mean NRS pain - patients with painDETECT score > 18, Mean (SD)	-2.94 (2.08)	-2.36 (2.31)	-0.59 (0.46) [-1.51:0.33]
CFB at wk 27 in mean NRS pain - patients with painDETECT score > 18, Mean (SD)	-3.05 (1.98)	-2.92 (2.22)	-0.13 (0.46) [-1.05:0.79]
CFB at wk 15 in mean NRS sleep, Mean (SD)	-2.57 (2.12)	-2.14 (2.14)	-0.43 (0.25) [-0.93:0.06]
CFB at wk 27 in mean NRS sleep, Mean (SD)	-2.72 (2.09)	-2.48 (2.06)	-0.24 (0.26) [-0.75:0.27]
CFB in the Euro Quality of Life Health State Profile (EQ-5D-5L) overall health index value at V6, n (%)	0.14 (0.17)	0.15 (0.23)	-0.01 (0.02) [-0.05:0.04]
CFB in the Euro Quality of Life Health State Profile (EQ-5D-5L) overall health index value at V9, n (%)	0.14 (0.19)	0.17 (0.22)	-0.03 (0.02) [-0.08:0.01]
Number and percentage of patients with a clinically relevant change in the SF-12 mental component summary at V6, n (%)	51 (31.5%)	53 (34.9%)	0.90 [0.66:1.24]
Number and percentage of patients with a clinically relevant change in the SF-12 mental component summary at V9, n (%)	47 (30.9%)	52 (36.1%)	0.86 [0.62:1.18]
Number and percentage of patients with a minimal clinically relevant change in the SF-12 physical component summary at V6, n (%)	117 (72.2)	101 (66.4)	1.09 [0.94:1.26]

Number and percentage of patients with a minimal clinically relevant change in the SF-12 physical component summary at V9, n (%)	112 (73.7)	105 (72.9)	1.01 [0.88:1.16]
CFB in the RMDQ at V6, Mean (SD)	-4.5 (4.6)	-3.7 (5.1)	-0.74 (0.55) [-1.82:0.34]
CFB in the RMDQ at V9, Mean (SD)	-4.6 (4.8)	-4.3 (5.3)	-0.29 (0.58) [-1.44:0.85]
Number and percentage of patients with a minimal clinically relevant change in the RMDQ total score at V6, n (%)	112 (69.6)	84 (56.0)	1.24 [1.04:1.48]
Number and percentage of patients with a minimal clinically relevant change in the RMDQ total score at V9, n (%)	100 (65.8)	94 (65.7)	1.00 [0.85:1.18]
Number and percentage of patients experiencing meaningful improvement of symptoms (PGIC) at V6, n (%)	87 (54.4)	74 (48.7)	1.12 [0.90:1.39]
Number and percentage of patients experiencing meaningful improvement of symptoms (PGIC) at V9, n (%)	82 (53.9)	75 (52.1)	1.04 [0.84:1.28]

6 Ethics approval

Table S9: List of Independent Ethics Committees

Country	Party Type	Name	Address
Czech Republic	Central Ethics Committee	Multicentrická etická komise IKEM a FTN (Multicentric Ethics Committee IKEM and FTN)	Vídeňská 800 140 59 Praha 4, Czech Republic
Czech Republic	Local Ethics Committee 1	Místní etická komise VFN v Praze (Local Ethics Committee VFN in Prague)	Na Bojišti 1 128 08 Praha 2, Czech Republic
Czech Republic	Local Ethics Committee 2	Místní eticka komise Nemocnice Teplice (Local Ethics Committee Teplice Hospital)	Duchcovská 53 415 01 Teplice, Czech Republic
Czech Republic	Local Ethics Committee 3	Místní eticka komise Nemocnice Děčín (Local Ethics Committee Decin Hospital)	U Nemocnice 1 405 99 Děčín, Czech Republic

Germany	Central Ethics Committee	Ethik-Kommission der Medizinischen Hochschule Hannover	Carl-Neuberg-Str. 1 30625 Hannover
Germany	Local Ethics Committee 1	Ethik-Kommission an der Medizinischen Fakultät der Universität Rostock	St.-Georg-Str. 108 18055 Rostock, Germany
Germany	Local Ethics Committee 2	Ethik-Kommission bei der Landesärztekammer Hessen	Hanauer Landstr. 152 60314 Frankfurt am Main, Germany
Germany	Local Ethics Committee 3	Ethik-Kommission der Ärztekammer Hamburg	Weidestr. 122 b 22083 Hamburg, Germany
Germany	Local Ethics Committee 4	Ethik-Kommission der Sächsischen Landesärztekammer	Schützenhöhe 16 01099 Dresden, Germany
Germany	Local Ethics Committee 5	Ethik-Kommission der Ärztekammer Nordrhein	Tersteegenstr. 9 40474 Düsseldorf, Germany
Germany	Local Ethics Committee 6	Ethik-Kommission des Landes Sachsen-Anhalt	Kühnauer Str. 70 06846 Dessau-Roßlau, Germany
Germany	Local Ethics Committee 7	Ethik-Kommission der Landesärztekammer Thüringen	Im Semmicht 33 07751 Jena, Germany
Germany	Local Ethics Committee 8	Ethik-Kommission bei der Landesärztekammer Baden-Württemberg	Liebknechtstr. 33 70565 Stuttgart, Germany
Germany	Local Ethics Committee 9	Ethik-Kommission bei der Ärztekammer Niedersachsen	Berliner Allee 20 30175 Hannover, Germany
Germany	Local Ethics Committee 10	Ethik-Kommissionen bei der Ärztekammer Schleswig-Holstein	Bismarckallee 8-12 23795 Bad Segeberg, Germany
Germany	Local Ethics Committee 11	Ethik-Kommission an der Medizinischen Fakultät der RWTH Aachen	Wendlingweg 2 52074 Aachen, Germany
Germany	Local Ethics Committee 12	Ethik-Kommission der Landesärztekammer Brandenburg	Dreifertstr. 12 03044 Cottbus, Germany
Germany	Local Ethics Committee 13	Ethik-Kommission des Landes Berlin	Turmstr. 21, Haus A 10559 Berlin, Germany
Poland	Central Ethics Committee	Komisja Bioetyczna przy Okręgowej Izbie Lekarskiej w Lublinie	ul. Chmielna 4 20-079 Lublin, Poland
Spain	Central Ethics Committee	CEIm Hospital Universitari de Bellvitge (CEIm)	Bellvitge University Hospital C/ de la Feixa Llarga s/n, 08907 Hospitalet de Llobregat, Barcelona, Spain