

**BACKONJA 1998**

Backonja M, Beydoun A, Edwards KR, Schwartz SL, Fonseca V, Hes M, et al. Gabapentin for the symptomatic treatment of painful neuropathy in patients with diabetes mellitus: a randomized controlled trial. *JAMA* 1998;280 (21):1831–6. [PMID: 9846777]

| Withdrawals  | Efficacy  | Adverse events (general)                                    | Adverse events (specific)                             |
|--|---|---|---|
| <i>All-cause withdrawal</i><br>Gabapentin 14/84<br>Placebo 16/81 | <i>Difference in end-point mean pain score (placebo - gabapentin):</i><br>-1.2 (95% CI: -1.9 to -0.6) | <i>At least one AE</i><br>Gabapentin 70/84<br>Placebo 54/81 | <i>Dizziness</i><br>Gabapentin 20/84<br>Placebo 4/81  |
| <i>AE withdrawal</i><br>Gabapentin 7/84<br>Placebo 5/81          | <i>PGIC much or moderately improved</i><br>Gabapentin 47/84<br>Placebo 25/81                          | <i>Serious AE</i><br>Gabapentin 3/84<br>Placebo 2/81        | <i>Somnolence</i><br>Gabapentin 19/84<br>Placebo 5/81 |
| <i>LoE withdrawal</i><br>Gabapentin 1/84<br>Placebo 5/81         | <i>At least 50% reduction in pain (CTR)</i><br>Gabapentin 39/84<br>Placebo 16/81                      | <i>Deaths</i><br>Gabapentin 0/84<br>Placebo 0/81            |   |
|  | <i>PGIC much improved (CTR)</i><br>Gabapentin 33/84<br>Placebo 12/81                                  |   |   |
|  | <i>PGIC moderately or much improved (CTR)</i><br>Gabapentin 47/84<br>Placebo 25/81                    |   |   |

**AE:** Adverse event; **LoE:** Lack of effect; **PGIC:** Patient Global Impression of Change

**BONE 2002**

Bone M, Critchley P, Buggy DJ. Gabapentin in postamputation phantom limb pain: a randomized, double-blind, placebo-controlled, cross-over study. *Regional Anesthesia and Pain Medicine* 2002;**27**(5):481–6. [DOI: 10.1053/rapm.2002.35169]

| Withdrawals                           | Efficacy  | Adverse events (general) | Adverse events (specific)   |
|---------------------------------------|---|--------------------------|---|
| No data on where withdrawals occurred | No dichotomous data<br>Significant benefit for gabapentin by week 6 for pain.<br><br><i>Change in average weekly pain score between baseline and end-point (gabapentin vs placebo):</i><br>-3.2 (SD: 2.1) vs -1.6 (SD: 0.7) | No data                  | <i>Somnolence</i><br>Gabapentin: 7/19<br>Placebo: 2/19<br><br><i>Dizziness</i><br>Gabapentin: 2/19<br>Placebo: 1/19 |

**CTR 945-1008**

Anonymous. Protocol A9451008. A 15 Week, randomized, double-blind, placebo-controlled, parallel-group, multi- center study of Neurontin (gabapentin) for efficacy and quality of life in patients with painful diabetic peripheral neuropathy. PhrmaWebSynopsis - Final 2 June 2005.

| Withdrawals  | Efficacy  | Adverse events (general)  | Adverse events (specific)   |
|--|---|---|---|
| <i>All-cause withdrawal</i><br>Gabapentin 64/200<br>Placebo 54/189 | <i>At least 30% reduction in pain</i><br>Gabapentin 113/200<br>Placebo 77/189 | <i>At least one AE</i><br>Gabapentin: 159/200<br>Placebo: 126/189 | <i>Somnolence</i><br>Gabapentin: 31/200<br>Placebo: 8/189   |
| <i>AE withdrawal</i><br>Gabapentin 27/200<br>Placebo 18/189        | <i>At least 50% reduction in pain</i><br>Gabapentin 77/200<br>Placebo 46/189  | <i>Serious AE</i><br>Gabapentin: 15/200<br>Placebo: 15/189        | <i>Dizziness</i><br>Gabapentin: 38/200<br>Placebo: 15/189   |
| <i>LoE withdrawal</i><br>Gabapentin 1/200<br>Placebo 4/189         |   | <i>Deaths</i><br>Gabapentin: 1/200<br>Placebo: 1/189              | <i>Asthenia</i><br>Gabapentin: 22/200<br>Placebo: 8/189<br><br><i>Peripheral oedema</i><br>Gabapentin: 33/200<br>Placebo: 7/189 |

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**GILRON 2005**

Gilron I, Bailey JM, Tu D, Holden RR, Weaver DF, Houlden RL. Morphine, gabapentin, or their combination for neuropathic pain. *New England Journal of Medicine* 2005;**352**(13):1324–34. [PMID: 15800228]

| Withdrawals                     | Efficacy   | Adverse events (general) | Adverse events (specific) |
|---------------------------------|--|--------------------------|---------------------------|
| 16 withdrawals during treatment | <i>At least moderate pain relief (5-point scale) for those completing a given treatment</i><br>Gabapentin: 27/44<br>Morphine: 35/44<br>Gabapentin + morphine: 32/41<br>Placebo: 13/42<br><br><i>Change in average weekly pain score between baseline and end-point (gabapentin vs morphine vs morphine + gabapentin vs placebo):</i><br>-1.6 vs -2.0 vs -2.7 vs -1.2 | Not interpretable        | Not interpretable         |

**GORDH 2008**

Gordh TE, Stubhaug A, Jensen TS, Arner S, Biber B, Boivie J, et al. Gabapentin in traumatic nerve injury pain: a randomized, double-blind, placebo-controlled, cross-over, multi-center study. *Pain* 2008;**138**(2):255–66. [DOI: 10.1016/j.pain.2007.12.011]

| Withdrawals  | Efficacy  | Adverse events (general)                                 | Adverse events (specific)                                |
|--|---|--|--|
| <i>All-cause withdrawal</i><br>Gabapentin: 11/120<br>Placebo: 11/120 | <i>Marked pain relief</i><br>Gabapentin: 18/98<br>Placebo: 5/98   | <i>Serious AE</i><br>Gabapentin: 5/120<br>Placebo: 1/120 | <i>Dizziness</i><br>Gabapentin: 39/120<br>Placebo: 9/120 |
| <i>AE withdrawal</i><br>Gabapentin: 7/120<br>Placebo: 3/120          | <i>Marked or moderate pain relief</i><br>Gabapentin: 31/98<br>Placebo: 14/98  |  |  |
| <i>LoE withdrawal</i><br>Gabapentin: 1/120<br>Placebo: 2/120         | <i>No pain relief</i><br>Gabapentin: 54/98<br>Placebo: 70/98  |  |  |
|  | <i>At least 50% pain relief</i><br>Gabapentin: 13/98<br>Placebo: 9/98   |  |  |
|  | <i>At least 30% pain relief</i><br>Gabapentin: 29/98<br>Placebo: 19/98  |  |  |
|  | Benefits from gabapentin over placebo for sleep and some aspects of quality of life   |  |  |
|  | <i>Change in average weekly pain score between baseline and end-point (gabapentin vs placebo): -7.2 (SD: 17.8) vs -6.9 (SD: 15.5) (study period 1) and -5.1 (SD: 11.6) vs -0.5 (SD: 9.7) (study period 2)</i> |  |  |

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**GORSON 1999**

Gorson KC, Schott C, Herman R, Ropper AH. Gabapentin in the treatment of painful diabetic neuropathy: a placebo controlled, double blind, crossover trial. *Journal of Neurology, Neurosurgery and Psychiatry* 1999;**66**:251–2. [PMID: 10071116]

| Efficacy  | Adverse events (general)  |
|---|---|
| <i>Moderate or excellent pain relief</i><br>Gabapentin: 17/40<br>Placebo: 9/40<br><br><i>Difference in change in pain score between gabapentin and placebo:</i><br>0.4 (95% CI: 0.1 to 0.5) | <i>At least one AE</i><br>Gabapentin: 12/40<br>Placebo: 4/40<br><br><i>Serious AE</i><br>Gabapentin: 0/40<br>Placebo: 0/40<br><br><i>Deaths (inferred)</i><br>Gabapentin: 0/40<br>Placebo: 0/40 |

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**HAHN 2004**

Hahn K, Arendt G, Braun JS, von Giesen HJ, Husstedt IW, et al. German Neuro-AIDS Working Group. A placebo- controlled trial of gabapentin for painful HIV-associated sensory neuropathies. *Journal of Neurology* 2004;**251**(10): 1260–6. [DOI: 10.1007/s00415-004-0529-6]

| Withdrawals   | Efficacy  | Adverse events (general)         | Adverse events (specific)  |
|---|---|----------------------------------|--|
| <i>All-cause withdrawal</i><br>Gabapentin: 1/15<br>Placebo: 1/11<br><br><i>AE withdrawal</i><br>Gabapentin: 1/15<br>Placebo: 0/11 | Improvement in pain and sleep interference with gabapentin and placebo, with sustained difference in sleep but not pain.<br><br><i>Difference in median weekly pain score between baseline and end-point (gabapentin vs placebo):</i><br>-2.6 vs -1.4 | No serious AE or deaths reported | <i>Somnolence</i><br>Gabapentin: 12/15<br>Placebo: 2/11<br><br><i>Dizziness</i><br>Gabapentin: 9/15<br>Placebo: 5/11<br><br><i>Disturbed gait</i><br>Gabapentin: 7/15<br>Placebo: 3/11 |

**AE:** Adverse event

**LEVENDOGLU 2004**

Levendoglu F, Ogun CO, Ozerbil O, Ogun TC, Ugurlu H. Gabapentin is a first line drug for the treatment of neuropathic pain in spinal cord injury. *Spine* 2004;**29**(7): 743–51. [DOI: 10.1097/01.BRS.0000112068.16108.3A]

| Withdrawals   | Efficacy  | Adverse events (general)                                  | Adverse events (specific)  |
|---------------|---|---|--|
| All completed | <i>Average fall in pain</i><br>Gabapentin: 62%<br>Placebo: 13%<br><br>Mean scores without standard deviations. No dichotomous results.<br><br><i>Percent change in pain score between baseline and end-point (gabapentin vs placebo):</i><br>62% vs 12% | <i>All-cause AE</i><br>Gabapentin: 13/20<br>Placebo: 5/20 | <i>Sedation</i><br>Gabapentin: 3/20<br>Placebo: 0/20<br><br><i>Oedema</i><br>Gabapentin: 3/20<br>Placebo: 0/20 |

**AE:** Adverse event



**RICE 2001**

Rice AS, Maton S, Postherpetic Neuralgia Study Group. Gabapentin in postherpetic neuralgia: a randomised, double blind, placebo controlled study. *Pain* 2001;**94**(2):215–24.  
[DOI: 10.1016/S0304-3959(01)00407-9]

| Withdrawals   | Efficacy   | Adverse events (general)   | Adverse events (specific)  |
|---|--|--|--|
| <i>All-cause</i> 22<br>Gaba 1800mg: 22<br>Gaba 2400mg: 23<br>Placebo: 17<br><br><i>AE withdrawal</i><br>Gaba 1800mg: 15<br>Gaba 2400mg: 19<br>Placebo: 7<br><br><i>LoE withdrawal</i><br>Gaba 1800mg: 4<br>Gaba 2400mg: 1<br>Placebo: 4 | <i>At least 50% reduction in mean pain score</i><br>Gaba 1800: 37/115<br>Gaba 2400: 37/108<br>Placebo: 16/111<br><br><i>PGIC very much or much improved</i><br>Gaba 1800: 44/115<br>Gaba 2400: 42/108<br>Placebo: 24/111<br><br><i>PGIC very much improved (CTR)</i><br>Gaba 1800: 18/115<br>Gaba 2400: 12/108<br>Placebo: 7/111<br><br><i>PGIC much improved (CTR)</i><br>Gaba 1800: 26/115<br>Gaba 2400: 30/108<br>Placebo: 17/111<br><br><i>Change in average weekly pain score between baseline and end-point (gabapentin 2400 mg vs gabapentin 1800 mg vs placebo):</i><br>-2.3 vs -2.2 vs -1.1 | <i>At least one AE</i><br>Gaba 1800: 81/115<br>Gaba 2400: 81/108<br>Placebo: 55/111<br><br><i>Serious AE</i><br>Gaba 1800: 3/115<br>Gaba 2400: 1/108<br>Placebo: 1/111<br><br><i>Death</i><br>Gaba 1800: 0/115<br>Gaba 2400: 1/108<br>Placebo: 0/111 | <i>Somnolence</i><br>Gaba 1800: 20/115<br>Gaba 2400: 22/108<br>Placebo: 7/111<br><br><i>Dizziness</i><br>Gaba 1800: 36/115<br>Gaba 2400: 36/108<br>Placebo: 11/111<br><br><i>Asthenia</i><br>Gaba 1800: 7/115<br>Gaba 2400: 6/108<br>Placebo: 4/111<br><br><i>Peripheral oedema</i><br>Gaba 1800: 6/115<br>Gaba 2400: 12/108<br>Placebo: 0/111 |

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## RINTALA 2007

Rintala DH, Holmes SA, Courtade D, Fiess RN, Tastard LV, Loubser PG. Comparison of the effectiveness of amitriptyline and gabapentin on chronic neuropathic pain in persons with spinal cord injury. *Archives of Physical Medicine and Rehabilitation* 2007;**88**(12):1547–60. [DOI: 10.1016/j.apmr.2007.07.038]

| Withdrawals    | Efficacy   | Adverse events (general) | Adverse events (specific) |
|----------------|--|--------------------------|---------------------------|
| 16/38 withdrew | <p>No dichotomous data. The paper claims statistical superiority of amitriptyline over gabapentin using paired t-tests for 22 patients completing all 3 phases. It also claims no benefit of gabapentin over placebo.</p> <p><i>Average pain rating during the 8th week of each study arm (gabapentin vs amitriptyline vs placebo, baseline: 5.6):</i><br/>4.9 vs 3.5 vs 5.1</p> | No dichotomous data      | No dichotomous data       |

**ROWBOTHAM 1998**

Rowbotham M, Harden N, Stacey B, Bernstein P, Magnus-Miller L. Gabapentin for the treatment of postherpetic neuralgia: a randomized controlled trial. *JAMA* 1998;**280** (21):1837–42. [PMID: 9846778]

| Withdrawals   | Efficacy   | Adverse events (general)  | Adverse events (specific)  |
|---|--|---|--|
| <i>All-cause</i><br>Gabapentin: 24<br>Placebo: 21     | <i>PGIC moderate or much improved</i><br>Gabapentin: 47/113<br>Placebo: 14/116 | <i>At least one AE</i><br>Gabapentin: 84/113<br>Placebo: 60/116                                       | <i>Somnolence</i><br>Gabapentin: 31/113<br>Placebo: 6/116        |
| <i>AE withdrawal</i><br>Gabapentin: 21<br>Placebo: 14 | <i>PGIC CTR much improved</i><br>Gabapentin: 21/113<br>Placebo: 6/116          | <i>Minor AE (treatment related)</i><br>Gabapentin: 62/113<br>Placebo: 32/116                          | <i>Dizziness</i><br>Gabapentin: 27/113<br>Placebo: 6/116         |
| <i>LoE withdrawal</i><br>Gabapentin: 0<br>Placebo: 2  | <i>PGIC CTR moderately improved</i><br>Gabapentin: 26/113<br>Placebo: 8/116    | <i>Serious AE (treatment related)</i><br>Gabapentin: 0/113 (10/113 CTR)<br>Placebo: 0/116 (5/116 CTR) | <i>Ataxia</i><br>Gabapentin: 8/113<br>Placebo: 0/116             |
|   | <i>No change in pain</i><br>Gabapentin: 23%<br>Placebo: 60%                    | <i>Death:</i><br>Gabapentin: 0/113<br>Placebo: 1/116  | <i>Peripheral oedema</i><br>Gabapentin: 11/113<br>Placebo: 4/116 |
|   | <i>No change/worse in pain</i><br>Gabapentin: 26%<br>Placebo: 68%              |   |  |

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**SERPELL 2002**

Serpell MG, Neuropathic pain study group. Gabapentin in neuropathic pain syndromes: a randomised, double- blind, placebo-controlled trial. *Pain* 2002;**99**(3):557–66. [DOI: 10.1016/S0304-3959(02)00255-5]

| Withdrawals  | Efficacy  | Adverse events (general)  | Adverse events (specific)  |
|--|---|---|--|
| <i>All-cause withdrawals</i><br>Gabapentin: 32/153<br>Placebo: 41/152<br><br><i>AE withdrawals</i><br>Gabapentin: 24/153<br>Placebo: 25/152<br><br><i>LoE withdrawals</i><br>Gabapentin: 1/153<br>Placebo: 5/152 | <i>At least 50% reduction in pain</i><br>Gabapentin: 32/153<br>Placebo: 22/152<br><br><i>PGIC very much or much improved</i><br>Gabapentin: 48/153<br>Placebo: 22/152<br><br><i>PGIC very much improved CTR</i><br>Gabapentin: 18/153<br>Placebo: 9/152<br><br><i>PGIC much improved CTR</i><br>Gabapentin: 30/153<br>Placebo: 13/152<br><br><i>Change in average weekly pain score between baseline and end-point (gabapentin vs placebo):</i><br>-1.5 vs -1.0 | <i>At least one AE</i><br>Gabapentin: 117/153<br>Placebo: 103/152<br><br><i>Serious AE</i><br>Gabapentin: 4/153<br>Placebo: 4/152<br><br><i>Deaths</i><br>Gabapentin: 0/153<br>Placebo: 2/152 | <i>Somnolence</i><br>Gabapentin: 22/153<br>Placebo: 8/152<br><br><i>Dizziness</i><br>Gabapentin: 37/153<br>Placebo: 12/152 |

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**SIMPSON 2001**

Simpson DA. Gabapentin and venlafaxine for the treatment of painful diabetic neuropathy. *Journal of Clinical Neuromuscular Disease* 2001;**3**(2):53–62. [PMID: 19078655]

| Withdrawals   | Efficacy   | Adverse events (general)                                   | Adverse events (specific)   |
|---|--|--|---|
| <i>All-cause withdrawal</i><br>Gabapentin: 3/30<br>Placebo: 3/30<br><br><i>AE withdrawal</i><br>Gabapentin: 2/30<br>Placebo: 2/30<br><br><i>LoE withdrawal</i><br>Gabapentin: 1/30<br>Placebo: 1/30 | <i>PGIC moderate or much improved</i><br>Gabapentin: 15/30<br>Placebo: 7/30<br><br><i>Mean change in pain score compared to baseline (gabapentin vs placebo):</i><br>-2.4 vs 0.4 | No deaths reported, and no serious adverse events reported | <i>Somnolence</i><br>Gabapentin: 6/27<br>Placebo: 1/27<br><br><i>Dizziness</i><br>Gabapentin: 6/27<br>Placebo: 1/28 |

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**SMITH 2005**

Smith DG, Ehde DM, Hanley MA, Campbell KM, Jensen MP, Hoffman AJ, et al. Efficacy of gabapentin in treating chronic phantom limb and residual limb pain. *Journal of Rehabilitation Research and Development* 2005;42(5): 645–54. [DOI: 10.1682/JRRD.2005.05.0082]

| Withdrawals             | Efficacy   | Adverse events (general) | Adverse events (specific) |
|-------------------------|--|--------------------------|---------------------------|
| No apparent withdrawals | <i>“Meaningful decrease in pain”</i><br>Gabapentin: 13/24<br>Placebo: 5/24<br><br><i>Change in average weekly pain score between baseline and end-point gabapentin vs placebo):</i><br>-0.9 vs -0.5 (phantom limb pain)<br>-1.2 vs -0.7 (stump pain) | No data                  | No data                   |