

# Gabapentin monotherapy for epilepsy

Ziganshina L., Gamirova R., Abakumova T.

Kazan Federal University, 420008, Kremlevskaya 18, Kazan, Russia

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## Abstract

© 2017 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd. This is a protocol for a Cochrane Review (Intervention). The objectives are as follows: To assess the effects of gabapentin monotherapy for people with epileptic partial seizures with and without secondary generalisation.

<http://dx.doi.org/10.1002/14651858.CD012710>

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## References

- [1] Al-Bachari S, Pulman J, Hutton JL, Marson AG. Gabapentin add-on for drug-resistant partial epilepsy. *Cochrane Database of Systematic Reviews* 2013, Issue 7. [DOI: 10.1002/14651858.CD001415.pub2]
- [2] American Academy of Neurology (AAN). Treatments for refractory epilepsy. [www.tools.aan.com/professionals/practice/pdfs/clinician\\_ep\\_treatment\\_e.pdf](http://www.tools.aan.com/professionals/practice/pdfs/clinician_ep_treatment_e.pdf) (accessed September 2016).
- [3] Banerjee PN, Filippi D, Allen Hauser W. The descriptive epidemiology of epilepsy - a review. *Epilepsy Research* 2009;85(1):31-45.
- [4] Bazil CW, Morrell MJ, Pedley TA. Epilepsy. In: Rowland LP editor(s). *Merritt's Neurology*. 11th Edition. Philadelphia: Lippincott Williams & Wilkins, 2005:990-1008.
- [5] Cockerell OC, Johnson AL, Sander JW, Hart YM, Shorvon SD. Remission of epilepsy: results from the National General Practice Study of Epilepsy. *Lancet* 1995;346(8968):140-4.
- [6] Veritas Health Innovation. Melbourne, Australia. Covidence systematic review software. Veritas Health Innovation. Melbourne, Australia, 2016.
- [7] De Boer HM, Mula M, Sander JW. The global burden and stigma of epilepsy. *Epilepsy & Behavior* 2008;12(4):540-6.
- [8] Deeks JJ, Higgins JPT, Altman DG. Chapter 9: Analysing data and undertaking meta-analyses. In: Higgins JPT, Green S, editor(s). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from [www.cochrane-handbook.org](http://www.cochrane-handbook.org). The Cochrane Collaboration, 2011. Available from [www.cochrane-handbook.org](http://www.cochrane-handbook.org).
- [9] DerSimonian R, Laird N. Meta-analysis in clinical trials. *Controlled Clinical Trials* 1986;7(3):177-88.
- [10] European Medicines Agency (EMA) committee for medicinal products for human use (CHMP). Summary information on referral opinion pursuant to Article 30 of Council Directive 2001/83/EC for Neurontin and associated names. [www.ema.europa.eu/docs/en\\_GB/document\\_library/Referrals\\_document/Neurontin\\_30/WC500009304.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Neurontin_30/WC500009304.pdf) (accessed September 2016).
- [11] Federal guideline. Federal guideline for use of medicines [www.booksite.ru/fulltext/ruk/ovo/dst/vom/66\\_1.htm](http://www.booksite.ru/fulltext/ruk/ovo/dst/vom/66_1.htm) (accessed September 2016).
- [12] Fisher RS, Acevedo C, Arzimanoglou A, Bogacz A, Cross JH, Elger CE, et al. A Practical Clinical Definition of Epilepsy. *Epilepsia* 2014;55:475-82.
- [13] Glauser T, Ben-Menachem E, Bourgeois B, Cnaan A, Chadwick D, Guerreiro C, et al. ILAE treatment guidelines: evidence-based analysis of antiepileptic drug efficacy and effectiveness as initial monotherapy for epileptic seizures and syndromes. *Epilepsia* 2006;47(7):1094-120. [DOI: 10.1111/j.1528-1167.2006.00585.x]

- [14] Glauser T, Ben-Menachem E, Bourgeois B, Cnaan A, Guerreiro C, Kälviäinen R, et al. Updated ILAE evidence review of antiepileptic drug efficacy and effectiveness as initial monotherapy for epileptic seizures and syndromes. *Epilepsia* 2013;54(3):551-63.
- [15] Goldenberg MM. Overview of drugs used for epilepsy and seizures: etiology, diagnosis, and treatment. *Pharmacy and Therapeutics* 2010;35(7):392-415.
- [16] Brozek J, Oxman A, Schunemann H. GRADEpro Version 3.6 for Windows. GRADE Working Group, 2004.
- [17] Gøtzsche PC. *Deadly Medicines and Organised Crime. How Big Pharma has Corrupted Healthcare*. London, United Kingdom: Radcliffe Publishing Ltd, 2013.
- [18] Higgins JPT, Altman DG, Sterne JAC. Chapter 8: Assessing risk of bias in included studies. In: Higgins JP, Green S, editor(s). *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011)*. The Cochrane Collaboration, 2011. Available from [handbook.cochrane.org](http://handbook.cochrane.org).
- [19] Higgins JPT, Deeks JJ. Chapter 7: Selecting studies and collecting data. In: Higgins JP, Green S, editor(s). *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011)*. The Cochrane Collaboration, 2011. Available from [handbook.cochrane.org](http://handbook.cochrane.org).
- [20] International conference on harmonisation of technical requirements for registration of pharmaceuticals human use (ICH) Expert Working Group. Post-approval safety data management: definitions and standards for expedited reporting E2D. [www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E2D/Step4/E2D\\_Guideline.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2D/Step4/E2D_Guideline.pdf) (accessed September 2016).
- [21] ILAE Commission on Antiepileptic Drugs of the International League Against Epilepsy. Considerations on designing clinical trials to evaluate the place of new antiepileptic drugs in the treatment of newly diagnosed and chronic patients with epilepsy. *Epilepsia* 1998;39(7):799-803.
- [22] Jennum P, Gyllenberg J, Kjellberg J. The social and economic consequences of epilepsy: a controlled national study. *Epilepsia* 2011;52(5):949-56. [DOI: 10.1111/j.1528-1167.2010.02946.x]
- [23] Krumholz SD, Egilman DS, Ross JS. Study of neurontin: titrate to effect, profile of safety (STEPS) trial: a narrative account of a gabapentin seeding trial. *Archives of Internal Medicine* 2011;171(12):1100-7. [DOI: 10.1001/archinternmed.2011.241]
- [24] Kwan P, Brodie MJ. Early identification of refractory epilepsy. *The New England Journal of Medicine* 2000;342(5):314-9.
- [25] Lefebvre C, Manheimer E, Glanville J. Chapter 6: Searching for studies. In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011)*. The Cochrane Collaboration, 2011. Available from [handbook.cochrane.org](http://handbook.cochrane.org).
- [26] Mantel N, Haenszel W. Statistical aspects of the analysis of data from retrospective studies of disease. *Journal of the National Cancer Institute* 1959;22(4):719-48.
- [27] Marson AG, Kadir ZA, Hutton JL, Chadwick DW. The new antiepileptic drugs: a systematic review of their efficacy and tolerability. *Epilepsia* 1997;38(8):859-80.
- [28] Marson AG, Al-Kharusi AM, Alwaidh M, Appleton R, Baker GA, Chadwick DW, et al. The SANAD study of effectiveness of carbamazepine, gabapentin, lamotrigine, oxcarbazepine, or topiramate for treatment of partial epilepsy: an unblinded randomised controlled trial. *Lancet* 2007;369(9566):1000-15.
- [29] Marson AG, Al-Kharusi AM, Alwaidh M, Appleton R, Baker GA, Chadwick DW, et al. The SANAD study of effectiveness of valproate, lamotrigine, or topiramate for generalised and unclassifiable epilepsy: an unblinded randomised controlled trial. *Lancet* 2007;369(9566):1016-26.
- [30] McClean MJ. Gabapentin. *Epilepsia* 1995;36(Suppl 2):72-86.
- [31] Megiddo I, Colson A, Chisholm D, Dua T, Nandi A, Laxminarayan R. Health and economic benefits of public financing of epilepsy treatment in India: an agent-based simulation model. *Epilepsia* 2016;57(3):464-74. [DOI: 10.1111/epi.13294]
- [32] MoH RF. Instruction for use of a medicinal preparation Neurontin [www.grls.rosminzdrav.ru/Grls\\_View\\_v2.aspx?routingGuid=f8d2a60d-de8a-4306-8558-34c1c53a5fa7&t=2016](http://www.grls.rosminzdrav.ru/Grls_View_v2.aspx?routingGuid=f8d2a60d-de8a-4306-8558-34c1c53a5fa7&t=2016): (accessed September 2016).
- [33] Morris GL. Gabapentin. *Epilepsia* 1999;40(Suppl 5):S63-70.
- [34] National Institute for Health and Care Excellence (NICE). *Epilepsies: diagnosis and management*. [www.nice.org.uk/guidance/cg137/resources/epilepsies-diagnosis-and-management-35109515407813](http://www.nice.org.uk/guidance/cg137/resources/epilepsies-diagnosis-and-management-35109515407813) (accessed September 2016).
- [35] Pfizer. Neurontin, prescribing information. [www.media.pfizer.com/files/products/uspi\\_neurontin.pdf](http://www.media.pfizer.com/files/products/uspi_neurontin.pdf) (accessed September 2016).
- [36] Pitkänen A, Schwartzkroin PA, Moshé SL. *Models of Seizures and Epilepsy*. Burlington: Elsevier. ISBN 9780080457024, 2005:539.
- [37] Nordic Cochrane Centre, The Cochrane Collaboration. *Review Manager 5 (RevMan 5)*. Version 5.3. Copenhagen: Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

- [38] Schunemann HJ, Oxman AD, Vist GE, Higgins JPT, Deeks JJ, Glasziou P, et al. Chapter 12: Interpreting results and drawing conclusions. In: Higgins JP, Green S, editor(s). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from [handbook.cochrane.org](http://handbook.cochrane.org).
- [39] Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of epilepsy in adults. [www.healthcareimprovementscotland.org](http://www.healthcareimprovementscotland.org); [www.sign.ac.uk/pdf/SIGN143.pdf](http://www.sign.ac.uk/pdf/SIGN143.pdf) (accessed September 2016).
- [40] St. Louis EK. Minimizing the Adverse effects of Epilepsy Therapies: Principles and Practice. In: EK St. Louis, DM Ficker, TJ O'Brien editor(s). *Epilepsy and the Interictal State: Co-morbidities and Quality of Life*. Chichester, UK: John Wiley & Sons, Ltd, 2015. [DOI: 10.1002/9781118951026.ch10]
- [41] Steinman MA, Bero LA, Chren MM, Landefeld CS. Narrative review: the promotion of gabapentin: an analysis of internal industry documents. *Annals of Internal Medicine* 2006;145(4):284-93.
- [42] Steinman MA, Harper GM, Chren MM, Landefeld CS, Bero LA. Characteristics and impact of drug detailing for gabapentin. *PLoS Med* 2007;4(4):e134. [DOI: 10.1371/journal.pmed.0040134]
- [43] U.S. Food, Drug Administration (FDA). Information for healthcare professionals: suicidal behavior and ideation and antiepileptic drugs. [www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm100192.htm](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm100192.htm) (accessed September 2016).
- [44] U.S. Food, Drug Administration (FDA). Full prescribing information. Neurontin. [www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/020235s060,020882s043,021129s042lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020235s060,020882s043,021129s042lbl.pdf) (accessed September 2016).
- [45] Walker MC, Sander JW. Difficulties in extrapolating from clinical trial data to clinical practice: the case of antiepileptic drugs. *Neurology* 1997;49(2):333-7.
- [46] Weston J, Bromley R, Jackson CF, Adab N, Clayton-Smith J, Greenhalgh J, et al. Monotherapy treatment of epilepsy in pregnancy: congenital malformation outcomes in the child. *Cochrane Database of Systematic Reviews* 2016, Issue 11. [DOI: 10.1002/14651858.CD010224.pub2]
- [47] World Health Organization (WHO). Epilepsy Fact sheet N°999. [www.who.int/mediacentre/factsheets/fs999/en/](http://www.who.int/mediacentre/factsheets/fs999/en/) (accessed September 2016).
- [48] Ziganshina LE, Abakumova T. Cerebrolysin for acute ischaemic stroke. *Cochrane Database of Systematic Reviews* 2015, Issue 6. [DOI: 10.1002/14651858.CD007026.pub3]