Table F-4. Prior or concurrent AED use in controlled studies comparing innovator versus generic antiepileptic drugs

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Study, Year | Group | N | Untreated(%) | Carbamazepine(%) | Phenytoin(%) | Valproid Acid (%) | CombinationTherapy (%) |
| Unspecified Innovator and Brand Antiepileptic Drug Products |
| Rascati, 2009 | Cases | 991 | 0 | - | - | - | - |
| Controls | 2973 | 0 | - | - | - | - |
| Zachry, 2009 | Cases | 416 | 0 | - | - | - | - |
| Controls | 1248 | 0 | - | - | - | - |
| Devine, 2010 | Cases | 2949 | 0 | - | - | - | 42.9 |
| Controls | 8847 | 0 | - | - | - | 22.4 |
| Labiner, 2010a | Branded carbamazepine, gabapentin, phenytoin, primidone, zonisamide (manufacturer not reported) | 18,125 | 0 | - | - | - | - |
| Carbamazepine, gabapentin, phenytoin, primidone, zonisamide (manufacturer not reported) |  | 0 | - | - | - | - |
| Labiner, 2010b | Branded carbamazepine, gabapentin, phenytoin, primidone, zonisamide (manufacturer not reported) | 15,500 | 0 | - | - | - | - |
| Carbamazepine, gabapentin, phenytoin, primidone, zonisamide (manufacturer not reported) |  | 0 | - | - | - | - |
| Carbamazepine |
| Kauko, 1974 | Tegretol (Ciba-Geigy) Tablets | 20 | 0 | 100 | - | - | 80 |
| Generic Carbamazepine (Laake Oy) Tablets |  |  |  |  |  |  |
| Glende, 1983 | Tegretol (Ciba-Geigy) Tablets | 5 | 0 | 100 | - | - | Some were reported as receiving combination therapy |
| Carbamazepine (AWD Dresden) Tablets |  |  |  |  |  |  |
| Jumao-as, 1989 | Tegretol (Ciba-Geigy) Tablets | 10 | - | 100 | 10 | - | 40 |
| Generic Carbamazepine (Parke Davis) Tablets |  |  |  |  |  |  |

| Table F-4. Prior or Concurrent AED Use in controlled studies comparing innovator versus generic antiepileptic drugs (continued) |
| --- |
| Study, Year | Group | N | Untreated(%) | Carbamazepine(%) | Phenytoin(%) | Valproid Acid (%) | CombinationTherapy (%) |
| Hartley, 1990 | Tegretol (Ciba-Geigy) | 23 | 56.5 | 43.5 | - | - | - |
| Carbamazepine (Ethical Generics) |  |  |  |  |  |  |
| Hartley, 1991 | Tegretol (Ciba-Geigy) Tablets | 12 | - | - | - | - | - |
| Carbamazepine (Ethical Generics) Tablets |  |  |  |  |  |  |
| Oles, 1992a | Tegretol (Ciba-Geigy) Tablets | 20 | 0 | 100 | 0 | 0 | 0 |
| Carbamazepine (Lemmon Co) Tablets |  |  |  |  |  |  |
| Oles, 1992b | Tegretol (Ciba-Geigy) Tablets | 20 | 0 | 100 | - | - | - |
| Carbamazepine (Lemmon Co) Tablets |  |  |  |  |  |  |
| Reunanen, 1992 | Tegretol Retard (Ciba-Geigy) Tablets | 20 | 0 | 100 | 15 | 25 | - |
| Carbamazepine Slow Release (Laakefarmos) Tablets |  |  |  |  |  |  |
| Silpakit, 1997(N=18) | Tegretol (Ciba-Geigy) Tablets | 18 | 0 | 100 | 0 | 5.6 | 38.9 |
| Carbamazepine (Central Poly) Tablets |  |  |  |  |  |  |
| Carbamazepine (Condrugs) Tablets |  |  |  |  |  |  |
| Carbamazepine (Pharmaland) Tablets |  |  |  |  |  |  |
| Aldenkamp, 1998(N=12) | Tegretol (Ciba-Geigy) Tablets | 12 | 0 | 100 | 0 | 0 | 0 |
| Generic (Pharmachemie) Tablets |  |  |  |  |  |  |
| Generic (Pharbita) Tablets |  |  |  |  |  |  |
| Garnett, 2005 | Tegretol (Novartis) Tablets | 275 | - | 0 | 12.7 | 4.4 | - |
| Generic (Various/Unspecified) Tablets | 705 | - | 0 | 17.0 | 8.9 | - |
| LeLorier 2008d | Tegretol CR (manufacturer not reported) | 851 | 0 | 100 | - | - | 51.8 |
| Carbamazepine CR (manufacturer not reported) |  |  |  |  |  |  |
| Clobazam |
| Andermann, 2007b | Frisium (manufacturer not reported) | 1600 | 0 | - | - | - | - |
| Clobazam (manufacturers not reported) |  |  |  |  |  |  |
| LeLorier, 2008b | Frisium (manufacturer not reported) | 1060 | 0 | - | - | - | 93.9 |
| Clobazam (manufacturer not reported) |  |  |  |  |  |  |
| Gabapentin |
| LeLorier, 2008c | Neurontin (manufacturer not reported) | 202 | 0 | - | - | - | 83.2 |
| Gabapentin (manufacturer not reported) |  |  |  |  |  |  |
| Lamotrigine |
| Andermann, 2007a | Lamictal (GlaxoSmithKline) | 1142 | 0 | 0 | 0 | 0 | 71.1 |
| Lamotrigine (manufacturers not reported) |  |  |  |  |  |  |
| LeLorier, 2008a | Lamictal (GlaxoSmithKline)  | 671 | 0 | 19.2 | - | 15.2 | 82.7 |
| Lamotrigine (manufacturer(s) not reported) |  |  |  |  |  |  |
| Nielsen, 2008a | Lamictal (manufacturer not reported) | 9 | 0 | - | - | 11.1 | 55.6 |
| Lamotrigine (Copyform, Hexal, Ratiofarm, Ratiopharm, Farma, Actavis, Stada)  |  |  |  |  |  |  |
| Levetiracetam,Oxcarbazepine,Phenobarbital or Primidone,Phenytoin |
| Lund, 1974  | Epanutin (Parke-Davis) capsules | 9 | - | - | - | - | - |
| Phenytoin sodium (Leo) capsules |  |  |  |  |  |  |
| Chen, 1982 | Epanutin (Parke-Davis) capsules | 18 | - | Concurrent treatment was usually phenobarbital, primidone, or carbamazepine. | 100% | - | - |
| Phenytoin sodium (Boots) tablets |  |  |  |  |  |  |
| Phenytoin sodium (Cox) tablets |  |  |  |  |  |  |
| Phenytoin sodium (Kerfoot) tablets |  |  |  |  |  |  |
| Phenytoin sodium (McCarthy UK) tablets |  |  |  |  |  |  |
| Hodges, 1986 | Phenytoin (Parke-Davis) capsules | 19 | - | - | - | - | - |
| Phenytoin (Boots) tablets |  |  |  |  |  |  |
| Phenytoin (Evans) tablets |  |  |  |  |  |  |
| Kishore, 1986 | Dilantin (Parke-Davis, India) capsules  | 15 | - | - | - | - | - |
| Phenytoin (Epsolin, Cadila) tablets  | 15 |  |  |  |  |  |
| Phenytoin (Eptoin, Boots India) tablets  | 15 |  |  |  |  |  |
| Phenytoin (Epileptin, Indian Drugs and Pharmaceuticals) capsules | 15 |  |  |  |  |  |
| Mikati, 1992a  | Dilantin (Parke-Davis) capsules | 10 | 0 | 0 | 100% | 0 | 0 |
| Phenytoin (Phenytex, manufacturer not reported) capsules |  |  |  |  |  |  |
| Soryal, 1992a  | Epanutin (Parke-Davis) capsules | 14 | - | - | - | - | - |
| Phenytoin sodium (Evans) tablets |  |  |  |  |  |  |
| Phenytoin sodium (APS) tablets |  |  |  |  |  |  |
| Phenytoin sodium (Cox) tablets |  |  |  |  |  |  |
| Phenytoin sodium (Kerfoot) tablets |  |  |  |  |  |  |
| Phenytoin sodium (Regent) tablets |  |  |  |  |  |  |
| Topiramate |
| Duh, 2009 | Topamax (Ortho-McNeil) | 875 | - | - | - | - | 70%, products not reported |
| Topiramate (Various manufacturers) – Single Product Users | 331 | - | - | - | - | 71%, products not reported |
| Topiramate (Various manufacturers) – Multiple Product Users | 99 | - | - | - | - | 72%, products not reported |
| Paradis, 2009b | Topamax (Ortho-McNeil) | - | - | - | - | - | 78.9%, products not reported |
| Topiramate (Various manufacturers) | - |  |  |  |  |  |
| Valproic Acid |
| Vadney, 1997 | Depakene (Abbott) | 64 | - | - | - | - | - |
| Valproic acid (Solvay) |  |  |  |  |  |  |
| Andermann, 2007c | Depakene (manufacturer not reported) | 2017 | 0 | - | - | 100 | - |
| Valproic Acid (manufacturers not reported) |  |  |  |  |  |  |

- = not reported; N = sample size

aCrossover Study

bReports on same database as Duh 2009