

Appendix 5: Reference list of included zanamivir trials [posted as supplied by author]

1. 167-101. GSK. Investigation of the efficacy of GG167 (zanamivir) in the treatment of influenza viral infections (late Phase II study: dose comparison study). Data on file.
2. JNAI-01. GSK. Investigation of the efficacy of CG167 in the treatment of influenza viral infections (phase II study)(Protocol NoJNAI-01) Double blind, double dummy, randomized, placebo controlled, parallel group, multicenter study to investigate safety and route of administration of CG167 when inhaled, CG167 10mg, or the combination of inhaled CG167 10mg plus intranasal CG167 6.4mg, administered twice daily for 5 days in the treatment of influenza A and B viral infections. Data on file.
3. JNAI-04. GSK. A multicenter two way layout randomized placebo-controlled double-blind trial parallel group comparative trial on the efficacy and safety of GG167 (zanamivir) 10mg twice a day and 20mg twice a day in the treatment of influenza type A and type B infections (late Phase II study: dose comparison study) (Protocol No.JNAI-04). Data on file.
4. JNAI-07. GSK. A multicenter two way layout randomized placebo-controlled double-blind trial parallel group comparative trial on the efficacy and safety of GG167 (zanamivir) 10mg twice a day and 20mg twice a day in the treatment of influenza type A and type B infections (late Phase II study: dose comparison study) (Protocol No.JNAI-07). Data on file.
5. NAI30008. No authors listed. A double-blind, randomized, placebo-controlled, parallel group, multi-center study to investigate the efficacy and safety of inhaled zanamivir 10 mg administered twice daily for five days in the treatment of influenza in patients 12 years or over diagnosed with asthma or chronic obstructive pulmonary disease. Data on file.
6. NAI30009. Alfors S, Keene O, Grice R, Hammond J, Hendricks V, Martin N, et al. A double-blind, randomized, placebo-controlled, parallel-group, multicenter study to investigate the efficacy and safety of zanamivir (GG167) 10 mg administered by inhalation twice daily for five days in the treatment of symptomatic influenza A and B viral infections in children ages 5-12. Data on file.
7. NAI30010. Hunter S, Reilly L, Sharp S, West M, Alfors S, Hammond J, et al. A double-blind, randomized, placebo-controlled, parallel-group, multicenter study to investigate the efficacy and safety of inhaled zanamivir (GG167) 10 mg administered once a day for 10 days in the prevention of transmission of symptomatic influenza A and B viral infections within families. Data on file.
8. NAI30011. No authors listed. A randomised, double-blind, placebo-controlled study to evaluate the impact of inhaled zanamivir treatment on workplace attendance due to influenza A and B infections. Data on file
9. NAI30012. No authors listed. A double-blind, randomised, placebo-controlled, parallel-group, multicentre study to investigate the efficacy and safety of inhaled zanamivir 10 mg administered twice daily for five days in the treatment of symptomatic influenza A and B viral infections in subjects aged over 65 years. Data on file.
10. NAI30015. No authors listed. A double-blind, randomised, placebo-controlled, parallel-group, multicentre study to investigate the efficacy and safety of inhaled zanamivir 10mg administered twice daily for five days in the treatment of symptomatic influenza A and B viral infections in armed services personnel. Data on file.
11. NAI30020. No authors listed. A double-blind, randomised, placebo-controlled, multicenter study in 2 parallel groups, to investigate the efficacy and safety of inhaled

- zanamivir (10 mg bd. via Diskhaler), for 5 days, in high risk patients with symptomatic influenza A and / or B infection. Data on file Synopsis only available.
12. NAI30028. No authors listed. A double-blind, randomised, placebo-controlled, multicenter study in 2 parallel groups, to investigate the efficacy and safety of inhaled zanamivir (10 mg bd via Diskhaler), for 5 days, in children aged 5 to 12 years with symptomatic influenza A and / or B infection. Data on file.
 13. NAI30031. No authors listed. A double-blind, randomised, placebo-controlled, parallel-group, multicentre study to investigate the efficacy and safety of inhaled zanamivir 10 mg administered once a day for 10 days in the prevention of transmission of symptomatic influenza A and B viral infections within households. Data on file.
 14. NAI30034. No authors listed. A double-blind, randomized, placebo-controlled, parallel-group, multicentre study to investigate the efficacy and safety of inhaled zanamivir 10 mg administered once a day for 28 days in the prevention of symptomatic influenza A and B viral infections in community-dwelling high-risk populations. Data on file.
 15. NAIA/B2008. No authors listed. A double-blind, randomized, placebo-controlled, multicenter, parallel-group study to investigate the efficacy and safety of zanamivir administered twice or four times a day for the treatment of influenza A and B viral infections. Data on file.
 16. NAIA/B2009. No authors listed. A double-blind, randomised, placebo-controlled, multicentre, parallel-group study to demonstrate the efficacy and safety of zanamivir in the prevention and/or progression of influenza A and B viral infections. Data on file.
 17. NAIA2005. MacLeod A, Gummer M, Raniga K, Hirst H, Keene O, Ossi M, et al. A double-blind, randomised, placebo-controlled multi-centre study to investigate the efficacy and safety of inhaled and intranasal zanamivir in the treatment of influenza A and B viral infections. Data on file.
 18. NAIA2006. No authors listed. A double-blind, randomised, placebo-controlled multicentre study to investigate the efficacy and safety of zanamivir therapy in the prevention of progression of influenza A and B viral infections. Data on file.
 19. NAIA3002. Elliott M, Flack N, Keene O, Szymborski P, Vega R (PharmaResearch, Inc). A double-blind, randomized, placebo-controlled, parallel-group, multicenter study to investigate the efficacy and safety of inhaled zanamivir (GG167) 10 mg administered twice a day for five days in the treatment of symptomatic influenza A and B viral infections in adolescents and adults. Data on file.
 20. NAIA3003. No authors listed. A double-blind, randomized, parallel-group, multi-center study to investigate the efficacy and safety of inhaled zanamivir 10 mg administered once a day compared to the standard of care in controlling nursing home influenza outbreaks. Data on file.
 21. NAIA3004. No authors listed. A double-blind, randomized, placebo-controlled, parallel-group, multi-center study to investigate the efficacy and safety of inhaled zanamivir 10 mg once a day in controlling nursing home influenza outbreaks. Data on file.
 22. NAIA3005. Elliott M, Hunter S, Flack N, Crisp A, Szymborski P, Vega R. A double-blind, randomized, placebo-controlled, parallel-group, multicenter study to investigate the efficacy and safety of zanamivir (GG167) 10 mg administered once a day for 28 days in the prevention of symptomatic influenza A and B viral infections in community dwelling adults. Data on file.

23. NAIB2005. Leong J, Brennan J, Gummer M, Keene O, Wightman K. A double-blind, randomised, placebo-controlled, parallel-group, multi-centre study to investigate the efficacy and safety of inhaled plus intranasal zanamivir in the treatment of influenza A and B viral infections. Data on file.
24. NAIB2006. No authors listed. A double-blind, randomised, placebo-controlled, parallel-group, multicentre study to investigate the efficacy and safety of inhaled zanamivir in preventing progression of influenza A and B viral infections. Data on file.
25. NAIB2007. Perich R, Solterbeck A, Keene O, Leong J, Raniga K, MacLeod A. A double-blind, randomised, placebo-controlled, parallel-group, multi-centre study to investigate the efficacy and safety of inhaled and inhaled plus intranasal zanamivir in the treatment of influenza A and B viral infections. Data on file.
26. NAIB3001. Campion K, Gummer M, Keene O. A double-blind, randomized, placebo-controlled, parallel-group, multicenter study to investigate the efficacy and safety of zanamivir administered twice daily in the treatment of influenza A and B viral infections in adults. Data on file.
27. NAIB3002. Man CY, Keene ON, Challoner T (Challoner Associates). A double-blind, randomised, placebo-controlled, parallel-group, multicentre study to investigate the efficacy and safety of inhaled zanamivir (GG167) 10mg administered twice a day for five days in the treatment of symptomatic influenza A and B viral infections in adolescents and adults. Data o
28. PE-01. No authors listed. A trial to investigate efficacy to reduce development of influenza symptoms in influenza infected patients treated with GG167 (protocol number PE-01 phase II clinical trial). A double-blind double-dummy, randomized, placebo-controlled, parallel group, multicenter study to investigate the efficacy reducing development of influenza symptoms and, safety and rout of administration of GG 157 when orally inhaled GG 167 10 mg, 6.4 mg nebulized intranasally or the combination of inhaled GG167 10 mg plus intranasal GG167 6.4 mg was administered twice day for 5 days in the treatment of influenza A and B viral infections. Data on file.