

From: David Morton  
Sent: Friday, March 10, 2006 11:23 AM  
To: NIEHS NICEATM  
Subject: Safety and potency testing of Botulinum toxin

Dear Sirs,

I am a veterinarian with experience of devising humane endpoints in research with a specific interest in vaccines and toxin testing. Some 20 years ago I developed a clinical endpoint for tetanus toxin and since then I have been involved in various HEP assessments. The UK Joint Working Group on Refinement (supported by the BVA Animal Welfare Fdn, UFAW, RSPCA and FRAME) is going to be looking at the issue of HEPs and I shall probably chair it. I attach some references that may help you decide if I am able to help.

Thanks

David Morton

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MORTON, D.B. & TOWNSEND, P. (1995) Dealing with adverse effects and suffering during animal research In revised version of 'Laboratory Animals - an introduction for experimenters'. pp 215- 231 Ed. A.A. Tuffery Publrs John Wiley & Sons Ltd, Chichester, UK. ISBN 0 471 95257 5

MORTON, D.B. (1996) The use of clinical signs as humane endpoints in experimental animal safety evaluation studies. Paper prepared for the OECD.

OECD (2001) Environmental Health and Safety Publications Series on Testing and Assessment No. 19 Guidance Document on the Recognition, Assessment, and Use of Clinical Signs as Humane Endpoints for Experimental Animals Used in Safety Evaluation Environment Directorate <http://www.oecd.org/ehs/test/mono19.pdf>

MORTON, D.B. (1997) Ethical and Refinement Aspects of Animal Experimentation. In: Veterinary Vaccinology. pp. 763 - 785. Eds. Pastoret, P.-P., Blancou, J., Vannier, P. & Verscheuren, C. Publrs. Elsevier Science BV. pp. 853. ISBN 0-444-81968-1

Morton, D.B. (1998) The importance of non-statistical design in refining animal experimentation. ANZCCART Facts Sheet. ANZCCART News 11, No. 2 June 1998 Insert. pp12. Publrs. ANZCCART PO Box 19 Glen Osmond, SA5064, Australia.

Cussler, K., Morton, D.B. & Hendriksen, C.F.M. (1998) Klinische Endpunkte als Ersatz für die Bestimmung der Letalitätsrate bei Tollwutinfektionsversuchen zur Impfstoffprüfung. ALTEX (Alternativen zu Tierexperimenten) Supplement 98: 40 - 42.

Morton, D.B. (1999) Refinement of In Vivo Tests. 187 - 193. Proceedings of Conference on Alternatives to Animals in the Development and Control of Biological Products for Human and Veterinary Use. Eds Brown F., Hendriksen C., Sesardic T. Developments in Biological Standardization. No. 101:ISBN 3-8055-6953-X. Publrs Karger, Basel, Switzerland.

Morton, D.B. (1999) Ethical aspects of the use of Animal Models of Infection. In: Handbook of Animal Models of Infection. Eds. Otto Zak, 1998 ISBN 0-12-775390-7 Publishers: Academic Press. Pp. 29-48

Cussler, K., Morton, D.B. & Hendriksen, C.F.M. (1999) Possibilities for the use of humane endpoints in vaccine potency tests. In: Programme and Abstracts of the 3rd World Congress on Alternatives and Animal Use in the Life Sciences. Page 138. Aug 29 to Sept. 2 Bologna 1999. Special issue of ATLA.

Hendriksen CFM, Steen B, Visser J, Cussler K, Morton, D.B. & Streijger, F. (1999) The evaluation of humane endpoints in pertussis vaccine potency testing. In: Humane Endpoints in Animal Experiments for Biomedical Research. Proceedings of the Intl Conference, 22-25 Nov 1998 Zeist, The Netherlands. Eds. CFM Hendriksen & DB Morton. pp106-113. ISBN 1-85315-429-6 Publrs Royal Soc Med. London WIM 8AE (5%)

Morton, D.B. (1999) Humane end points in animal experimentation for biomedical research: Ethical, legal and practical aspects. In: Humane Endpoints in Animal Experiments for Biomedical Research. Proceedings of the Intl Conference, 22-25 Nov 1998 Zeist, The Netherlands. Eds. CFM Hendriksen & DB Morton. pp 5-12. ISBN 1-85315-429-6 Publrs Royal Soc Med. London WIM 8AE (100%)

Cussler, K., Morton, DB & Hendriksen, CFM (1999) Humane endpoints in vaccine research and quality control. In: Humane Endpoints in Animal Experiments for Biomedical Research. Proceedings of the Intl Conference, 22-25 Nov 1998 Zeist, The Netherlands. Eds. CFM Hendriksen & DB Morton. pp 95-101. ISBN 1-85315-429-6 Publrs Royal Soc Med. London WIM 8AE

Morton, D.B. (2000) A Systematic Approach for Establishing Humane Endpoints. ILAR Journal 41: No 2. 80-86

Morton DB and Hau J (2002) Welfare Assessment and Humane Endpoints Chapter 18 PP 457-486 In: 2nd Ed of the CRC Handbook of Laboratory Animal Science Vol. 1. Essential Principles and Practices. Eds Jann Hau and Gerald L Van Hoosier, Jr. Publrs CRC Press ISBN 0-8493-1086-5

Morton, DB (2003) Refinement of animal testing - same gain less pain. In: Replacement, reduction and refinement of the use of animals in the quality control of vaccines. Proceedings of the International Symposium pp19-23. Strasbourg 7-8 Nov 2002. Council of Europe.