

A proposal for Defining New Criteria for Idiopathic Inflammatory Myopathies

International Myositis Classification Criteria
Project Workshop
Washington DC
November 10- 11, 2005

Why do we need new criteria?

- Scientific molecular development
- Improved knowledge on disease mechanisms
- Drug development
- Well defined clinical and laboratory phenotypes

Chronology of Published Diagnostic/Classification Criteria for IIM

- Medsger et al. 1970, Am. J. Med 48:715 (IIM)
- DeVere & Bradley 1975, Brain 98:637 (IIM)
- Bohan & Peter 1975, NEJM 292:344 and 403 (PM/DM)
- Dalakas 1991, NEJM 325:1487 (PM/DM/IBM)
- Griggs et al. 1995, Ann Neurol 38:705 (IBM)
- Tanimoto et al. 1995, J Rheum 22:668 (PM/DM)
- Targoff et al. 1997, Curr Opin Rheum 9:527 (IIM)
- Mastaglia & Phillips 2002, RDCNA 28:723 (PM/DM/IBM)
- Van der Meulen et al. 2003, Neurol 61:316 (PM/DM/other)
- Dalakas & Hohlfeld 2003, Lancet 362:971 (PM/DM)
- Hoogendijk, Amato et al. 2003, Neuro Dis 14:337 (PM/DM)
- Troyanov Y et al. 2005, Medicine 84:231

IIM Criteria Summary

- Based on clinical impressions rather than data analyses and none have been fully tested for sensitivity or specificity using appropriately powered studies against all the appropriate disease confounders
- Recent splits in criteria by different specialties threaten to create difficulties in comparing studies and clinical trials in the future
- New large, multicentered and multispecialty studies and analyses are needed to meet this need

IIM Criteria - Why Now?

- Development of technology
 - Biopsy analyses
 - Autoantibodies
 - MRI
- International networks for myositis have been developed
- The IMACS network developed Outcome Measures and Definitions of Improvement

International Myositis Classification Criteria Project - Goal

- To develop and validate classification criteria for IIM and subgroups in adults and children for clinical research
- Endorsement by professional organisations

Proposed International Myositis Classification Criteria Project - Support

- American College of Rheumatology/European League Against Rheumatic Diseases grant funded to support meetings
- Application submitted to The Myositis Association for funds to support possible additional pathologic, immunologic and statistical analyses

Proposed International Myositis Classification Criteria Project - Timeline

- Oct. 2004 – Planning meeting held at NIH
- Sept. 2005 – Pilot project performed
- Nov. 2005 – Variables and project plans finalized
- Aug. 2006 – Collection of initial data on 1200 pts
- Dec. 2006 – Complete analyses of initial data to determine needs for additional disorders
- July 2007 – Completion of all data collection
- Sept. 2007 – Completion of all data analyses
- Nov. 2007 – Meeting or email vote on final proposed criteria and possible future plans

Project participants

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Goal of 1st workshop

- Define list of Variables
- Define Comparator groups
- Workplan to deliver classification criteria
- Discuss other funding possibilities
- Discuss - Endorsement by Neurology, Dermatology organisations