IMACS STUDIES

Over the last decade IMACS has undertaken a number of projects aimed at achieving its goals of improving the lives of children and adults who suffer from myositis by discovering better therapies and understanding the causes of these diseases. Central to these efforts have been a number of studies to develop consensus and standards on the conduct and reporting of adult and juvenile myositis investigations, including outcome measures, clinical trial design and classification of patients with myositis. Listed here is information on the studies that IMACS has reviewed and endorsed. Feel free to contact the Lead Investigators to learn more about or participate in these studies.

Completed IMACS Research Projects

IMACS Project I. Developing and validating core set measures of myositis disease activity and damage

Primary Objectives: Develop and validate new tools to assess disease activity and damage for patients with adult and juvenile dermatomyositis and polymyositis

Start Date: 2000

Completion Date: 2010

Lead Investigators:
- Lisa Rider, M.D.
  Deputy Chief, Environmental Autoimmunity Group
  NIEHS
  riderl@mail.nih.gov
- Frederick W. Miller, M.D., Ph.D.
  Deputy Chief, Clinical Research Branch and Principal Investigator
  millerf@mail.nih.gov
- David A. Isenberg , M.D., F.R.C.P., M.D.
  ARC Diamond Jubilee Professor of Rheumatology
  d.isenberg@ucl.ac.uk

Publications:


Rider LG, Werth VP, Huber AM, Alexanderson H, Rao AP, Ruperto N, Herbelin L, Barohn R, Isenberg D, Miller FW. Measures of adult and juvenile dermatomyositis, polymyositis, and inclusion body myositis: Physician and Patient/Parent Global Activity, Manual Muscle Testing (MMT), Health Assessment Questionnaire (HAQ)/Childhood Health Assessment Questionnaire (C-HAQ), Childhood Myositis Assessment Scale (CMAS), Myositis Disease Activity Assessment Tool (MDAAT), Disease Activity Score (DAS), Short Form 36 (SF-36), Child Health Questionnaire (CHQ), physician global damage, Myositis...
IMACS Project II. Determining clinically meaningful change in core set activity measures and developing preliminary definitions of improvement

Primary Objectives:
1. Determine clinically meaningful change in core set activity measures
2. Develop preliminary definitions of improvement as response criteria for adult and juvenile dermatomyositis and polymyositis

Start Date: 2002

Completion Date: 2004

Lead Investigators:
- Lisa Rider, M.D.
  Pediatric Rheumatology
  NIEHS
  riderl@mail.nih.gov
- Frederick W. Miller, M.D., Ph.D.
  Deputy Chief, Clinical Research Branch and Principal Investigator
  millerf@mail.nih.gov
- Ann Reed
  ann.reed@duke.edu

Publications:


IMACS Research Project III. Consensus guidelines for the design and conduct of myositis clinical trials

Primary Objectives:
Develop consensus in the design of myositis clinical trials, including classification criteria for myositis

Start Date: 2002
Completion Date: 2005

Lead Investigators:
Chet Oddis M.D.
cvo5@pitt.edu
- Lisa Rider, M.D.
  Pediatric Rheumatology
  NIEHS
  riderl@mail.nih.gov
- Frederick W. Miller, M.D., Ph.D.
  Deputy Chief, Clinical Research Branch and Principal Investigator
  millerf@mail.nih.gov
- Ann Reed
  ann.reed@duke.edu

Publications:

IMACS Project IV. Dyslipidemia in Myositis Survey

Primary Objectives:
To examine the frequency of lipid profile abnormalities in patients with myositis

Start Date: 2009
Completion Date: 2010

Lead Investigators:
- Christina Charles-Schoeman
ccharles@mednet.ucla.edu

Publications:

IMACS Project V. Identification of a candidate core-set of fitness and strength tests for patients with childhood or adult idiopathic inflammatory myopathies

**Primary Objectives:**
To develop consensus on a candidate core-set of fitness and strength tests for children and adults with myositis

**Start Date:** 2013

**Completion Date:** 2015

**Lead Investigators:**
- Djamilla K.D. van der Stap
djamillavanderstap@gmail.com
- Tim Takken Ph.D.
  T.Takken@umcutrecht.nl

**Publications:**

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**Ongoing IMACS Research Projects**

**IMACS Project VI. IMACS Outcomes Data Repository**

**Primary Objectives:**
Develop a repository of databases of myositis natural history studies and therapeutic trials that have all collected the IMACS disease activity and damage core set measures, as well as core demographic and clinical data, for use by myositis researchers.

For further information on the IMACS Outcomes Data Repository, including use of the data that has been deposited, please see: [IMACS Outcomes Repository Data Use Guidelines](#).

**Start Date:** 2004

**Completion Date:** Ongoing
Lead Investigators:

- Lisa Rider, M.D.
  Pediatric Rheumatology
  NIEHS
  riderl@mail.nih.gov

- Frederick W. Miller, M.D., Ph.D.
  Deputy Chief, Clinical Research Branch and Principal Investigator
  millerf@mail.nih.gov

Publications:
None

IMACS Project VII. International Myositis Classification Criteria Project

Primary Objectives:
To develop new preliminarily validated classification criteria for adult and juvenile dermatomyositis, adult polymyositis and inclusion body myositis.

For further information on the International Myositis Classification Criteria Project, please see International Myositis Classification Criteria Project.

Start Date: 2004
Completion Date: Ongoing

Lead Investigators:

- Ingrid Lundberg, M.D., Ph.D.
  Ingrid.Lundberg@medks.ki.se

Publications:
None

IMACS Project VIII. Standards of Treatment for Adults with Myositis and different Phenotypes - STAMP

Primary Objectives:
To define standard approaches to treat myositis phenotypes

Start Date: 2011
Completion Date: Ongoing

Lead Investigators:

Lead Investigators:

- Lisa Christopher-Stine
  lchrist4@jhmi.edu
- Hector Chinoy
  Hector.Chinoy@srft.nhs.uk
- Neil McHugh
  Neil.McHugh@rnhrd.nhs.uk
- Sarah Tansley
  sarah.tansley@rnhrd.nhs.uk
- Lyubo Dourmishev
  l_dourmishev@yahoo.com

Publications:


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IMACS Project IX. ACR-EULAR Project to Revise the Definition of Improvement and Major Clinical Response for Adult and Juvenile Dermatomyositis and Adult Polymyositis

Primary Objectives:
To develop new response criteria for adult and juvenile dermatomyositis and polymyositis, including criteria for minimal and major response for use as endpoints in myositis therapeutic trials.

Start Date: 2012

Completion Date: Ongoing

Lead Investigators:

- Lisa Rider, M.D.
  Pediatric Rheumatology
  NIEHS
  riderl@mail.nih.gov
- Nicola Ruperto M.D. MPH
IMACS Project X. Development of an internationally agreed minimal dataset for juvenile dermatomyositis (JDM) for clinical and research use

Primary Objectives:
To develop consensus on minimal elements to include in a JDM dataset to be used for clinical and research purposes

Start Date: 2014

Completion Date: Ongoing

Lead Investigators:
- Liza McCann
  lizamccann@btinternet.com

Publications:


IMACS Project XI. Identification of novel biomarkers and clinical or gene signature phenotypes in myositis that predict disease activity, damage, and prognosis

Primary Objectives:
Goals of this project include defining predictive biomarkers of disease course in different myositis subsets.

**Start Date:** 2015

**Completion Date:** Ongoing

**Lead Investigators:**
TBA

**Publications:**
None

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**IMACS Project XII. Guidelines for cancer screening and follow-up of myositis phenotypes**

**Primary Objectives:**
Objectives of this project include derivation/definition of consensus guidelines for cancer screening in patients diagnosed with idiopathic inflammatory myopathies.

**Start Date:** 2015

**Completion Date:** Ongoing

**Lead Investigators:**
- Rohit Aggarwal, M.D.
  
  aggarwalr@upmc.edu

**Publications:**
None

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**IMACS Project XIII. Screening, treatment, and monitoring of myositis-associated interstitial lung disease**

**Primary Objectives:**
Through the development of a combined retrospective/prospective database, the purpose of this project is to devise consensus guidelines for diagnosis, management, and outcomes assessment in myositis-associated ILD.

**Start Date:** 2015

**Completion Date:** Ongoing

**Lead Investigators:**
IMACS Project XIV. The role of rituximab and mycophenolate mofetil, without oral steroids, in the treatment of myositis

Primary Objectives:
This purpose of this project is to synthesize retrospective experience involving rituximab and mycophenolate mofetil (MMF) combination therapy in the treatment of myositis subsets (including myositis-associated ILD) as a foundation for future clinical trials using rituximab and MMF in the absence of corticosteroids.

Start Date: 2015

Completion Date: Ongoing

Lead Investigators:

- David A. Isenberg, M.D., F.R.C.P., M.D.
  ARC Diamond Jubilee Professor of Rheumatology
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Publications:
None