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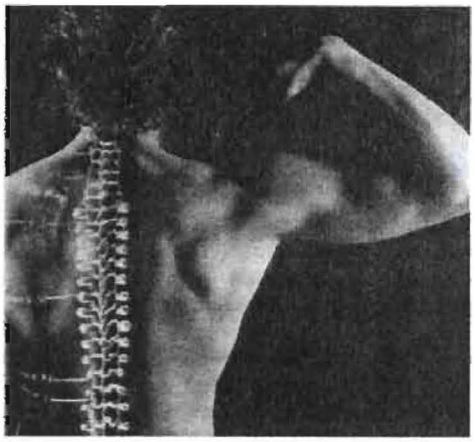
Pitt Gets $8 Million From the NIH to Lead Largest-Ever Study of Myositis



By Michele D. Baum

Researchers from the Division of Rheumatology and Clinical Immunology in Pitt's School of Medicine are leading a worldwide effort to study a treatment for a rare autoimmune disorder called myositis, thanks to a five-year, $8 million contract from the National Institute of Arthritis and Musculoskeletal and Skin Diseases, part of the National Institutes of Health (NIH).

Pitt Professor of Medicine Chester V. Oddis is principal investigator for the effort, which involves 36 other scientists from 18 states and five countries, including Canada, the Czech Republic, Sweden, the United Kingdom, and the United States.

Myositis is a general term for several conditions, including dermatomyositis, polymyositis, inclusion-body myositis, and juvenile forms of myositis.

Also known as inflammatory myopathies, they are musculoskeletal disorders characterized by muscle weakness thought to be autoimmune diseases. This means that the body's immune system, which normally fights infections and viruses, for reasons unknown turns on itself and attacks the muscle tissue and sometimes skin, joints, and lungs, causing rashes, arthritis, and shortness of breath.

The Pitt-led study will evaluate the effectiveness of a drug called rituximab in adults and children diagnosed with dermatomyositis (a disease that causes muscle weakness and rash) and adults diagnosed with polymyositis, which is not associated with a rash. The study investigators want to know whether rituximab improves symptoms of these diseases.

Rituximab is a monoclonal antibody used and approved since 1997 by the Food and Drug Administration (FDA) for the treatment of B-cell non-Hodgkin's lymphoma. It was approved in February 2006 for adult rheumatoid arthritis patients with an inadequate response to anti-TNF (tumor necrosis factor) agents. In the Pitt-led study, rituximab is considered to be experimental because it is not FDA-approved for the treatment of dermatomyositis or polymyositis.

Chester V. Oddis

The investigators believe that the symptoms of myositis are related to the presence of B cells in the blood, and rituximab is being given to reduce the number of blood B cells. This drug has been used in other research studies in patients with other rheumatologic and autoimmune diseases.

A total of 202 participants will be included in the study, including 152 adults and 50 children at 36 centers across North America and Europe, in a randomized, double blind, placebo-controlled, phase 2 trial.