Adults with Relapsing MS for Research Study

[IRB-HSR 19182]

**Description** | The University of Virginia Department of Neurology is conducting a research study to see if an investigational drug, ofatumumab, is superior to the standard of care treatment, teriflunomide, in patients with relapsing multiple sclerosis.

**UVA Principal Investigator:** Myla Goldman, MD
**Contact:** Margaret Keller, RN, MS
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We invite referring providers to consider enrolling their patients with multiple sclerosis in one of our clinical trials. Please visit uvahealth.com/neurologytrials for up-to-date information on our ongoing studies and trials.

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Our Team

The multidisciplinary team at the James Q. Miller Multiple Sclerosis Clinic features a broad team of specialists, including:

- MS-trained neurologists
- Neuropsychologists
- MS-certified nurse practitioners
- Clinical RN care coordinators
- Clinical research coordinators
- Social workers
- Physical therapists
- Occupational therapists
- Speech therapists

**J. Nicholas Brenton, MD**
Pediatric Neurology

**Kathleen Fuchs, PhD**
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**Myla Goldman, MD**
Neurology

**David Jones, MD**
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Neurology

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Children and Adolescents 10-17 for Multiple Sclerosis Study

[IRB-HSR 19290]

**Description** | The University of Virginia Department of Neurology is conducting a research study to see if an investigational drug, teriflunomide, is safe and helpful in treating multiple sclerosis in children and adolescents ages 10-17.

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Multiple Sclerosis

At the James Q. Miller Multiple Sclerosis Clinic, we provide comprehensive care for adults and children with multiple sclerosis (MS). Our specially trained multidisciplinary team of neurologists, physical and occupational therapists, social workers and neuropsychologists collaborate with other specialists across UVA Health System to ensure that every MS patient we treat benefits from a personalized plan of care. The result is an industry-leading, team-based approach that has earned us a Center for Comprehensive MS Care designation by the National Multiple Sclerosis Society.

Advanced MS Care

MS is a quickly advancing therapeutic field in neurology, with new and novel therapies offering exciting new avenues of treatment for patients. However, the side effect profile and immunosuppressant properties of these drugs have made the management of MS increasingly complex. Patients are best able to benefit from these new therapies when they partner with a physician who is specialty-trained in the management of the most current medications.

Indeed, the physicians and researchers at UVA are poised at the forefront of these therapies, leading investigator-initiated studies that seek to bring the bench to the bedside in contemporary MS care. This well-developed infrastructure allows us to track and manage the complex therapeutic programs of our patients with MS, ensuring each patient experiences the maximum benefit from their therapies in a safe, closely monitored environment.

Our collaborative relationship with UVA neuroimaging specialists is another important element that enables us to provide all-encompassing management for our MS patients. Our physicians have real-time access to MRI results, allowing patients to consult with their UVA doctor the same day that they have their MRI. Moreover, we hold a bimonthly conference to review patients’ images with our partner UVA neuroradiologists. This relationship allows us to better understand the disease process of medically complicated patients, which in turn allows us to choose therapies best suited to each patient’s individual needs.

Conditions Treated

At the James Q. Miller Multiple Sclerosis Clinic, we treat pediatric and adult patients with all forms of MS, including relapsing-remitting, primary progressive and secondary progressive.

We work with each patient to manage their MS symptoms — including ambulatory dysfunction, spasticity, fatigue, neurogenic bladder and cognitive dysfunction — through medications, lifestyle changes and counseling.

Our patients also deeply value our partnership with the National Multiple Sclerosis Society (NMSS). We have a representative from the NMSS at our clinic each week, offering educational materials for patients and families, as well as...
information on national resources that can help patients plan for their ongoing MS care. Our partnership with the NIMSS also provides patients and families access to an annual respite camp.

**Adult-Onset Multiple Sclerosis**

In addition to supporting our adult patients through the latest advances in MS medications, our multidisciplinary care includes physical, occupational, and speech therapy available weekly at our clinic.

In addition, a social worker partners with each patient to consider their short- and long-term care needs. We connect patients with support groups and community resources to help them navigate the care they will require over their lifetime.

**Pediatric-Onset Multiple Sclerosis**

Up to 10 percent of patients diagnosed with MS will experience the onset of MS symptoms in childhood or adolescence. The MS team at UVA includes a pediatric neurologist who specializes in pediatric-onset MS—a rarity among even highly regarded MS programs. This specialization allows us to provide the most advanced care to children and adolescents who are diagnosed with MS. Because we are one of the few centers to offer this specialized care, we treat pediatric patients with MS from throughout the commonwealth of Virginia and surrounding states.

Patients who are diagnosed with MS at this age often experience feelings of isolation, fear, and denial. To help address this unique issue, our pediatric MS program coordinates support networks aimed at helping these children connect with other children and young adults diagnosed with the disease. By doing this, we are able to provide peer-to-peer support that is vital for any young patient with a chronic illness, like MS.

**Additional Conditions**

Our specialization in inflammatory demyelinating disorders allows us to provide exceptional care to adult and pediatric patients with other diseases, including:

- Acute disseminated encephalomyelitis
- Neuromyelitis optica (NMO)
- Neurosarcoidosis
- Autoimmune encephalitis (e.g., anti-NMDA receptor encephalitis)
- Acquired demyelinating syndromes (e.g., transverse myelitis, optic neuritis)

**Referring a Patient**

We value our partnership with the primary care providers and specialists who refer patients to our MS program. We see a wide array of patients, from those for whom MS is not yet diagnosed, to those who have failed multiple therapies.

Here’s how our referral process works:

- We obtain the patient’s records, including imaging. We review these materials carefully to learn where the patient is in their diagnosis and disease course.
- The patient comes to the James O. Miller Multiple Sclerosis Clinic for a thorough evaluation, which may include MRI, sensory and visual evoked potential tests, lumbar puncture and blood tests.
- Our team reviews the results of the evaluation and creates an individualized plan of care.
- We provide the referring provider with a detailed summary of the evaluation and share the plan of care.
- If the patient can benefit from additional services, such as physical, occupational, or speech therapists, these members of our team are engaged in the plan of care.
- If the patient is a candidate for a new or novel therapy, one of our team’s nurse case managers works with the patient to understand the steps involved and provides coordination.

**Treatments such as infusions, injections, and oral therapies often require close monitoring, which we coordinate with the team and the patient.**
- If an injection therapy is chosen as treatment, a nurse practitioner on our team will provide personalized injection training.
- If the patient will undergo infusion therapy, a nurse case manager coordinates the patient’s plan of care with the UVA Infusion Center.
- When possible, we partner with the patient’s referring provider to manage the patient’s care locally, allowing the patient to come to our clinic on an annual or as-needed basis.
- Our team uses EpicCare Link to keep all referring providers up to date on their patient’s evaluations and therapies.

**Research**

We are proud to offer our patients with MS the opportunity to benefit from the groundbreaking translational research underway at UVA each and every day. Ongoing MS research at UVA includes investigator-initiated projects examining prognostic factors in pediatric and adult MS, as well as disease traits that impact relapse and recovery. These research efforts are yielding new and novel therapies that are improving the quality of life for patients with MS here and around the world.

Our robust MS research program and commitment to comprehensive care has earned us a special partnership with the ziMS Foundation, a nonprofit founded by Washington Nationals player and University of Virginia alumnus Ryan Zimmerman in honor of his mother, who was diagnosed with MS in 1995. Since its inception, the foundation has raised more than $1 million for research and program expansion at James O. Miller Multiple Sclerosis Clinic. We are honored by this gift and are committed to putting these funds toward improving the lives of patients with MS and finding a cure for this devastating disease.

**Clinical Trials and Research Studies**

Currently enrolling clinical trials at UVA focused on multiple sclerosis include:

**Research Study for Children and Adults with Multiple Sclerosis (IRB-HSR 18159)**

**Description** | The purpose of the study is to see if a particular diet therapy (a low-carbohydrate diet known as the modified Atkins diet) is effective and safe for use in people with relapsing MS. The study involves working with a personal dietitian to adhere to a strictly low-carbohydrate diet for six months.

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**Research Study for Adults with Relapsing-Remitting MS (IRB-HSR 16-493)**

**Description** | The purpose of the study is to determine whether vitamin D3 supplementation as an add-on to glatiramer acetate therapy will affect the relapse rate of MS. Study involves taking glatiramer acetate by injection, as well as one of two doses of vitamin D.

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**Research Study for Adults with Radiologically Isolated Syndrome (RIS) (IRB-HSR 18877)**

**Description** | The purpose of the study is to see if an investigational medication is an effective treatment for radiologically isolated syndrome (RIS). RIS is a condition in which people have MRI findings often associated with multiple sclerosis (MS), but have not been diagnosed with MS.

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