



Understanding Stem Cell Therapy for ALS

A Patient Guide from Auragens

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Advancing Regenerative Medicine: Treatments & Empathy Amplified by Science and Technology 2026

Welcome

Thank you for considering Auragens for your ALS care journey. We understand that living with Amyotrophic Lateral Sclerosis (ALS) brings unique challenges, and we're here to provide you with the most advanced, evidence-based regenerative medicine options available today.

This guide will help you understand how expanded umbilical cord mesenchymal stem cells (hUC-MSCs) from Wharton's Jelly, delivered through intravenous (IV) infusion, may help slow the progression of ALS. We've included scientific references throughout so you can explore the research further and come to your consultation fully informed.

1. Understanding ALS and Current Treatment Limitations

What is ALS?

Amyotrophic Lateral Sclerosis (ALS), sometimes called Lou Gehrig's disease, is a progressive neurodegenerative condition affecting the nerve cells (motor neurons) in your brain and spinal cord. These motor neurons control voluntary muscle movement — everything from walking and talking to breathing and swallowing.

As ALS progresses, motor neurons gradually deteriorate and die, leading to progressive muscle weakness, loss of mobility, difficulty speaking and swallowing, and eventually challenges with breathing.

Why Are Current Treatments Limited?

The FDA has approved several medications for ALS, including riluzole, edaravone, and combination therapies. While these can help slow progression for some patients, they typically offer modest benefits and do not stop or reverse the condition [1], [2]. Key limitations include:

- **Modest impact:** Current medications may extend survival by several months but do not halt progression.
- **Variable response:** Not all patients respond to available medications.
- **Side effects:** Some treatments come with significant side effects affecting quality of life.
- **No regenerative capacity:** Existing drugs do not repair damaged motor neurons or restore lost function.

This is why researchers and clinicians worldwide are exploring regenerative medicine approaches, including stem cell therapy, as potential complementary or alternative treatments that work through entirely different biological mechanisms [3], [4].

2. What Are hUC-MSCs from Wharton's Jelly?

Understanding Mesenchymal Stem Cells

Mesenchymal stem cells (MSCs) are specialized cells with remarkable healing and regenerative properties. Unlike embryonic stem cells, MSCs are adult stem cells that can be safely obtained from various tissues without ethical concerns.

What Makes Wharton's Jelly Special?

Wharton's Jelly is the soft, gelatinous tissue that surrounds the blood vessels inside the umbilical cord. After a healthy baby is born, this tissue — which would otherwise be discarded — can be collected and used as an exceptionally rich source of mesenchymal stem cells.

hUC-MSCs from Wharton's Jelly offer several unique advantages:

- **Young and potent:** These cells come from newborn tissue, making them more vigorous and capable of robust regenerative activity compared to cells from adult tissues.
- **Immunologically privileged:** They have low immunogenicity, meaning they're less likely to be rejected by your immune system, even though they come from a donor [5].
- **Abundant growth factors:** They naturally produce high levels of healing and protective molecules.
- **Ethical and safe:** Collection is non-invasive, painless, and poses no risk to mother or baby.

How Are the Cells Prepared?

At Auragens, we use only pharmaceutical-grade hUC-MSCs that are:

1. **Sourced ethically:** Collected from healthy, screened donors after normal, full-term births with informed consent, that we personally oversee from 2nd trimester of pregnancy with our OBGYN and maintain chain of custody throughout.
2. **Expanded in certified laboratories:** Grown under strict Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) standards to ensure purity, potency, and safety in our on site AABB accredited, ISO certified lab [1], [6].
3. **Rigorously tested:** Each batch undergoes extensive quality control testing for sterility, viability, and therapeutic potential internally and externally through 3rd party labs and government health institute.
4. **Cryopreserved:** Carefully frozen to maintain cell viability until the moment of your treatment.

The cells are then thawed, prepared, and administered fresh on the day of your treatment to ensure maximum therapeutic benefit.



Why Auragens: AABB Accreditation — The Gold Standard in Cellular Therapy

Auragens Stem Cell Center is proud to be AABB accredited — a critical distinction that sets us apart from unaccredited clinics.

What is AABB Accreditation?

AABB (Association for Advancement of Blood and Biotechnologies) is the internationally recognized leader in setting quality and safety standards for cellular therapies. AABB is a deemed status organization by the FDA and AABB accreditation represents the gold standard in the field — the most rigorous, comprehensive certification available for facilities that process and administer cellular products.

What Does AABB Accreditation Mean for You?

When you choose an AABB-accredited center like Auragens, you can trust that we meet the highest international standards in:

- **Cell Processing Excellence:** Our laboratory protocols follow strict, validated procedures ensuring every cell product meets pharmaceutical-grade quality specifications.
- **Donor Screening & Safety:** Comprehensive screening protocols ensure all donor tissue is thoroughly tested and meets stringent safety criteria.
- **Laboratory Practices:** Our facilities, equipment, and processes undergo regular inspection and must meet exacting standards for sterility, environmental control, and quality assurance.
- **Patient Safety:** From cell arrival through administration and follow-up, every step is designed and monitored to protect your safety.
- **Staff Expertise:** Our team maintains specialized training and competency requirements specific to cellular therapy.
- **Traceability & Documentation:** Complete tracking and documentation of every cell product ensures full accountability.
- **Continuous Quality Improvement:** Regular audits, proficiency testing, and quality reviews ensure we maintain excellence.

Why This Matters

The field of stem cell therapy is rapidly growing, but not all clinics meet the same standards. Many facilities operate without independent accreditation or oversight. AABB accreditation means an external, U.S., FDA, expert organization has thoroughly inspected and validated our practices — giving you independent verification, proven quality systems, and genuine peace of mind. When you choose Auragens, you're choosing a center that has been independently verified to meet the most stringent international standards for cellular therapy quality and safety.

AABB accreditation is not easy to achieve or maintain — it requires significant investment in infrastructure, training, quality systems, and ongoing compliance. We've made this commitment because you deserve nothing less than the highest standard of care.

3. How hUC-MSCs May Help Slow ALS Progression

hUC-MSCs don't work like traditional medications. Instead of targeting a single pathway, they act as "biological factories" that release hundreds of beneficial molecules and work through multiple complementary mechanisms to support your body's natural healing processes.

3.1 Neuroprotection: Shielding Your Motor Neurons

One of the most important ways hUC-MSCs may help is by protecting your existing motor neurons from further damage. These cells release protective factors that help stressed or injured neurons survive longer and function better [7], [8]. Think of it like providing a protective shield around vulnerable cells, helping them withstand the toxic environment that develops in ALS.

3.2 Neurotrophic Factor Secretion: Feeding Your Nervous System

hUC-MSCs naturally produce and release powerful growth factors that nourish and support nerve cells:

- **Brain-Derived Neurotrophic Factor (BDNF):** Promotes neuron survival and growth
- **Glial Cell Line-Derived Neurotrophic Factor (GDNF):** Protects motor neurons specifically
- **Nerve Growth Factor (NGF):** Supports nerve cell health and function
- **Vascular Endothelial Growth Factor (VEGF):** Improves blood flow and oxygen delivery

These neurotrophic factors act like "fertilizer" for your nervous system. Clinical studies have shown that after MSC treatment, levels of these beneficial factors increase in the cerebrospinal fluid of ALS patients, correlating with clinical stabilization [11], [18].

3.3 Immunomodulation: Rebalancing Your Immune System

In ALS, the immune system becomes overactive and contributes to motor neuron damage through chronic inflammation. hUC-MSCs have powerful immunomodulatory properties — they reduce harmful pro-inflammatory immune cells, increase beneficial regulatory immune cells, and shift the immune environment from destructive to protective. This immune rebalancing may help slow the inflammatory damage that accelerates ALS progression [12], [13], [14], [15].

3.4 Anti-Inflammatory Effects: Cooling the Fire

Chronic inflammation in the brain and spinal cord is a major driver of ALS progression. hUC-MSCs release anti-inflammatory molecules that help reduce this harmful inflammation, creating a more favorable environment for motor neuron survival. Studies show that after MSC treatment, inflammatory markers in the cerebrospinal fluid decrease while protective factors increase [16], [17], [18].

3.5 Exosome Signaling: Tiny Messengers with Big Impact

hUC-MSCs release tiny vesicles called exosomes — think of them as "care packages" filled with therapeutic proteins, genetic material, and signaling molecules that travel throughout your body delivering their healing cargo to cells that need support [19], [30]. Exosomes from hUC-MSCs reduce oxidative stress, promote cell survival, modulate inflammation, and support tissue repair — a sophisticated natural healing mechanism that works alongside the other therapeutic effects.

The Synergistic Effect

What makes hUC-MSC therapy particularly promising is that all these mechanisms work together simultaneously. Rather than targeting just one aspect of ALS, the cells provide comprehensive biological support that addresses multiple disease processes at once [20], [21].

4. Clinical Evidence and Research Findings

Over the past decade, multiple clinical trials have investigated mesenchymal stem cell therapy for ALS, with increasingly encouraging results. While this therapy is still considered investigational, the evidence base continues to grow.

Survival Benefits

One of the most significant findings comes from a 2020 study of 67 ALS patients treated with Wharton's Jelly-derived MSCs [2]:

- Median survival time increased two-fold compared to matched control patients.
- 70% reduction in risk of death in the treated group.
- Benefits observed regardless of whether symptoms started in the limbs or bulbar region (speech/swallowing).

These survival benefits were comparable to those seen with edaravone, one of the FDA-approved medications for ALS [2].

Disease Progression

Multiple studies have documented effects on disease progression, measured using the ALS Functional Rating Scale-Revised (ALSFRS-R), which tracks your ability to perform daily activities:

- 31.3% of patients showed decreased progression rates — their disease slowed after treatment [2].
- 49.3% maintained stable progression rates, suggesting the treatment prevented acceleration of decline [2].
- Female patients and those who responded well to the first treatment were more likely to benefit from subsequent treatments [2].

A 2021 meta-analysis found that intrathecal (spinal) injection of mesenchymal stem cells showed a transient positive effect on clinical progression as measured by ALSFRS-R scores [29].

Biomarker Changes

Research has shown that MSC therapy produces measurable biological changes:

- Increased neurotrophic factors in cerebrospinal fluid, supporting motor neuron health [18].
- Decreased inflammatory markers, indicating reduced harmful inflammation [18].
- Immune system rebalancing, with shifts toward protective rather than destructive responses [15], [28].

Response Patterns

It's important to understand that not everyone responds the same way. Some patients experience clear slowing of disease progression; others maintain stability without further decline; a smaller percentage may

not show measurable benefit. Factors that may influence response include disease stage, genetic factors, sex (females may respond better), and individual immune characteristics [2], [7].

Ongoing Research

The field continues to advance rapidly, with studies investigating optimal dosing, combination approaches with conventional medications, and biomarkers to predict who will respond best. A 2025 phase I study is currently comparing intravenous versus intrathecal administration of Wharton's Jelly MSCs to determine which route may be most effective [1].

Important Context

While these findings are encouraging, it's essential to maintain realistic expectations. Stem cell therapy is not a cure for ALS. Results vary significantly between individuals. The goal is to slow progression and potentially improve quality of life, not to reverse existing damage. More research is needed to fully understand optimal protocols and long-term outcomes. At Auragens, we're committed to staying at the forefront of this research.

5. Safety Profile: What the Research Shows

One of the most reassuring aspects of hUC-MSC therapy is its strong safety profile across multiple clinical trials involving hundreds of ALS patients.

No Serious Adverse Events

- The 2020 study of 67 ALS patients receiving Wharton's Jelly MSCs reported no serious adverse drug reactions [2].
- A 2019 safety study specifically examining intrathecal injection of Wharton's Jelly MSCs in ALS patients concluded the treatment was safe and well-tolerated [24].
- Multiple phase I and II trials have consistently reported no treatment-related serious adverse events [10], [22], [28].

Minor, Temporary Side Effects

When side effects do occur, they are typically mild and short-lived:

- **Post-procedure symptoms:** Some patients experience temporary headache or nausea following the procedure [2].
- **Mild fever:** Less than 10% of patients may experience a low-grade fever that resolves within 24–48 hours [2].
- **Injection site reactions:** Minimal discomfort at the IV site, similar to any intravenous procedure.

All reported side effects resolved quickly without complications or additional treatment [2], [24].

Why Are hUC-MSCs So Safe?

1. **Immunological compatibility:** hUC-MSCs from Wharton's Jelly have low immunogenicity, meaning they rarely trigger rejection or allergic reactions [5].
2. **No tumor formation:** Unlike some other cell types, MSCs do not form tumors or undergo uncontrolled growth [6].

3. Natural mechanisms: The cells work through natural biological processes rather than introducing foreign chemicals.

4. Rigorous screening: Donor screening and cell testing eliminate infectious disease risks.

Comparison to Conventional Treatments

The safety profile of hUC-MSC therapy compares very favorably to conventional ALS medications, which can cause liver function abnormalities (riluzole), bruising and gait disturbance (edaravone), and gastrointestinal side effects. In contrast, UC-MSC therapy has demonstrated minimal side effects in clinical studies [2], [24].

At Auragens, patient safety is our top priority. We carefully monitor vital signs before, during, and after treatment, any immediate reactions during infusion, and long-term outcomes through regular follow-up assessments.

6. What to Expect Next at Auragens

At Auragens, we've designed a comprehensive, patient-centered treatment experience that prioritizes your safety, comfort, and optimal outcomes.

Step 1: Comprehensive Consultation

Your journey begins with an in-depth consultation where we review your complete medical history and ALS progression, discuss your current symptoms and treatment goals, explain the science behind hUC-MSC therapy in detail, and develop a personalized treatment plan tailored to your needs. We encourage you to bring family members or caregivers and to come prepared with questions.

Step 2: Treatment Review

Following your medical consultation with our team, we will review the customized treatment plan, full schedule in Panama and answer any questions that you have, to provide full transparency and clarity into whether the decision to receive treatment at Auragens is right for you.

Our Commitment to Excellence

- **Evidence-based practice:** Using only protocols supported by scientific research.
- **Pharmaceutical-grade cells:** Producing the highest quality hUC-MSCs from certified, GMP-compliant laboratory.
- **AABB Accredited:** Meeting the gold standard for cellular therapy quality and safety.
- **Transparent communication:** Providing honest, realistic information about potential benefits and limitations.
- **Personalized care:** Treating you as an individual, not a protocol.
- **Ongoing education:** Staying current with the latest research and continuously improving our protocols.

7. Next Steps

Is hUC-MSC Therapy Right for You?

hUC-MSC therapy may be appropriate if you:

- Have a confirmed diagnosis of ALS.
- Are looking for treatment options beyond conventional medications.
- Understand that this is an investigational therapy with variable results.
- Have realistic expectations about potential benefits.
- Are in generally stable health apart from ALS.
- Are interested in a treatment approach with a strong safety profile.

Questions to Consider Before Your Consultation

1. What are my primary treatment goals? (Slowing progression, maintaining function, improving quality of life)
2. What is my current disease stage and rate of progression?
3. What conventional treatments have I tried, and how have I responded?
4. What are my concerns or questions about stem cell therapy?
5. What does my neurologist think about this approach?
6. What are my financial considerations and resources?

A Message of Hope

Living with ALS is undoubtedly challenging, but advances in regenerative medicine are opening new doors of possibility. While hUC-MSC therapy is not a cure, the growing body of research suggests it may offer a safe, biologically sophisticated approach to slowing disease progression and supporting your body's natural healing mechanisms.

At Auragens, we're honored to walk this journey with you. Our goal is to provide you with cutting-edge treatment options, compassionate care, and the information you need to make the best decisions for your health and quality of life.

With hope and dedication to your care,
The Auragens Patient Care Team

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The following peer-reviewed sources underpin the information in this guide. Click any link to explore the research further.

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This educational document is provided for informational purposes only and does not constitute medical advice. Individual results may vary. Please consult with your physician and the Auragens medical team to determine if UC-MSC therapy is appropriate for your specific situation.