

# Autologous muscle-derived cells may treat stress urinary incontinence

April 26 2009

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Researchers have confirmed that transplanting autologous muscle-derived cells (AMDC) into the bladder is safe at a wide range of doses and significantly improves symptoms and quality of life in patients with stress urinary incontinence. The study was presented at the 104th Annual Scientific Meeting of the American Urological Association (AUA) and showed that the injection of muscle-derived cells was well tolerated and significantly improved symptoms.

Researchers conducted two study phases on the efficacy and safety of muscle-derived cell transplantation. In the study phases, which are ongoing, 29 women (mean age of 49.5), whose stress urinary incontinence symptoms had not improved within a year of standard therapy, received cystoscope-assisted periurethral cell injections. At the three month follow-up appointment, participants could elect a second injection of the same dose. Follow-up occurred at one, three, six and 12 months after the last injection. Clinical outcomes were evaluated with a pad weight test, a voiding diary and validated quality of life questionnaires. In the first, double-blind phase, 20 [patients](#) were randomized into five groups to receive one, two, four, eight or 16 x 10<sup>6</sup> AMDCs. In the second, single-blind phase, nine patients were randomized into three groups to receive 32, 64, or 128 x 10<sup>6</sup> AMDCs.

Results showed that 86.2 percent of the 29 patients elected a second injection. To date, 17 patients have reached the 12-month follow-up appointment. No serious adverse events have been encountered. Minor events occurred at similar rates among all dose groups and included pain

and bruising at the muscle biopsy site, pain at the injection site, mild and self-limiting urinary retention and urinary tract infection. One patient experienced notably worsened incontinence. Quality of life measures improved in 68 percent of patients three months after the first injection and in 67 percent of patients three months after the second injection. Symptoms improved in 61 percent of patients at three months after the first injection and three months after the second injection. Urinary leaks were reduced after both injections. At 12 months, 13 of 17 patients (76.5 percent) reported an overall reduction in stress leaks and urgency compared to baseline; four reported no leaks.

"This study confirms that autologous muscle-derived cells constitute a safe and effective treatment for incontinence at various dosages," said Anthony Atala, MD, an AUA spokesman. "It is important to note that this therapy has few side effects and seems to improve symptoms for most patients in whom other therapies failed."

Source: American Urological Association

Citation: Autologous muscle-derived cells may treat stress urinary incontinence (2009, April 26) retrieved 21 November 2023 from

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