SHANKLE CLINIC

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About the Experimental Option of Immunoglobulin G (IgG) Therapy

Since about 2002, Dr. Shankle has treated approximately 50 patients with IVIG for up to 7 years. Using the FAST staging instrument to measure rate of functional decline, the results have been consistent in slowing the rate of decline compared to the patient's pre-treatment rate of functional decline.

We previously presented at conference proceedings that 80% of 16 Alzheimer's disease (**AD**) patients and 4 of 4 Lewy Body Disease (**LBD**) patients showed a 200% to 700% delay in the rate of functional decline when taking intravenous IgG (**IVIG**) for two or more years. This rate was in comparison to their pre-IgG treatment rate of decline. In patients who stopped IgG treatment, they declined at an intermediate rate between pre-IgG and on-IgG for up to 2 years, then resumed the pre-IgG treatment rate of decline.

There has been one FDA phase III trial of mild to moderate dementia AD patients treated with IVIG, which failed. There are many possible reasons why an FDA trial fails, only one of which is treatment inefficacy.

The cost of IVIG is prohibitive for most patients (thousands of dollars per month). The absorption of IgG from blood to brain is only 0.1%, which may be why it takes so much IgG when given intravenously, and why it is so expensive. I have therefore looked for other ways to deliver IgG more efficiently to the brain so that the cost can be reduced.

Intranasally delivered IgG may be much less expensive than IVIG because there is no blood-brain barrier when IgG is inhaled through the nose. This means that lower doses of inhaled IgG may deliver the same amount to the brain as higher doses of IVIG.

To date, Dr. Shankle has used intranasal IgG to treat 9 AD, 5 Lewy Body and 2 Parkinson's disease patients with very low dose IgG at a cost of $200 to $400 per month for the IgG itself. All patients have shown objective cognitive improvement in brain areas located near the points of entry of intranasally delivered IgG into the brain. One of the moderately demented Lewy Body patients showed dramatic improvement in balance, speech, hallucinations, and level of confusion within 2 months of intranasal IgG treatment.

However, brain areas further away from points of entry of intranasally delivered IgG into the brain have not shown improvement in more impaired patients given this very low dose of IgG intranasally.

The unknown factor is the percent absorption from the nasal cavity to the brain. Once that is known, then the intranasal dose can be adjusted to give an amount of IgG that is equivalent to the amount that gets into the brain when given intravenously.

The primary cost of this treatment is the inhaler technology, which currently costs $4,000 to $5,000 for the inhaler through Kurve Technology.

It is critical to deliver the IgG to the back of the nasal cavity so that IgG can pass through the pores in the bone separating the nose from the brain.

Intranasally inhaled IgG also enters the brainstem directly through the nerve fibers that provide sensation to the face (the Trigeminal Nerve), which is why it may be effective for LBD, and possibly Parkinson's disease, both of which show disease pathology early on in the upper brainstem.

With the understanding that this is an experimental treatment option with no certainty of a beneficial result, here is what needs to be done to try intranasal IgG treatment:

1. Upon your request, the Shankle Clinic will order a set of blood tests to assure that IgG is safe to give.
2. If there are no contraindications to giving IgG intranasally, then contact Marc Giroux at mgiroux@kurvetech.com, which makes the inhaler.
3. Marc can then train you on how to use the inhaler and arrange for its purchase.
4. Once obtained, Dr. Shankle will provide a prescription for intranasal IgG to Coast Hills Pharmacy, plus instructions on how to administer it.
5. The Shankle Clinic will then test cognition at 3 and 6 months after starting intranasal IgG to get one type of measure of treatment effect.
6. Other tests that can be used to measure treatment effect over a longer term
    a. (before and 1-3 years after being on intranasal IgG) are:
    b. A spinal fluid test for beta amyloid and neurofibrillary tau to measure their changes.
    c. A quantitative MRI.
    d. A PET scan for amyloid or tau, once they become clinically available.

You can find out more information by going to the Kurve technology website, www.kurvetech.com.

Dr. Shankle has no financial or proprietary interest in any aspect of treatment with intranasal IgG. He is cautiously optimistic about this form of treatment because both IVIG and intranasal IgG appear to consistently provide measurable improvement or delay in AD and LBD.

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Shankle Clinic for Memory and Cognitive Disorders