UPDATE: THE USE OF AIMSPRO, OR GOAT SERUM, IN MS

Aimspro is an injected experimental treatment made from the serum (the fluid portion of blood) of goats that have been inoculated with a variety of vaccines. The manufacturer, Daval International Ltd (East Sussex, UK), proposes that Aimspro may be useful in the treatment of multiple sclerosis and other inflammatory and neurological conditions because of its possible anti-inflammatory properties.

Many claims have been made for Aimspro. For a time some individuals with MS in the United Kingdom had received goat serum outside of clinical trials through a program of “informed consent” from general practitioners. Aimspro, an unlicensed drug, is no longer available through the informed consent program, but according to Daval International’s Web site (www.davalinternational.com) and other reports, the company expects to make it available in spring 2006 in the United Kingdom through a “Named Patient Basis,” where physicians who have registered with the manufacturer write prescriptions for the drug and their patients pay the costs.

Daval International Ltd was cited for misleading advertising about Aimspro on its Web site in July 2004 by the UK Medicines and Healthcare Products Regulatory Agency, and the company responded by removing most of its claims for the product.

Studies of Aimspro
There is little published evidence available to back up anecdotal claims about the effects of goat serum in MS.

- A controlled trial (where half of the participants received the treatment and half received placebo, a dummy treatment) was begun at St. George’s Hospital in South London. Eighty participants with secondary-progressive MS were involved. According to a March 2, 2005 announcement by the manufacturer, this trial was halted. No further information is available at this time.
• A small clinical trial of Aimspro was conducted at Oxford University in 12 individuals with MS with chronic visual impairment from optic neuritis. Full results have not yet been published, but an abstract was presented at the Association of British Neurologists and the proceedings of that meeting were published in the *Journal of Neurology, Neurosurgery and Psychiatry* in 2005 (76:1326). In this randomized, controlled, crossover trial, Aimspro or inactive placebo was injected under the skin once weekly for 3 weeks, after which those originally on placebo received treatment and vice versa. The most important planned outcome measures – known as the primary and secondary endpoints – were specific responses in visual evoked potential tests and the BOLD response in the visual cortex, an MRI-based measure of visual stimulation in the brain. There were no differences between those taking placebo and those taking treatment in either the primary or secondary endpoints.

There was slight improvement in a tertiary endpoint that tested peripheral visual field before and after treatment. According to the investigators, “this significance was lost when the effect of drug (post Aimspro – pre Aimspro) was compared to the effect of placebo (post placebo – pre placebo).” The investigators emphasized the need for further clinical trials to determine if their findings were valid.

• An uncontrolled, unblinded observational report was published in the *Journal of Clinical Neuroscience* (published early online in March 2006 doi:10.1016/j.jocn.2005.04.014) related to six individuals with secondary-progressive MS or relapsing-remitting MS and stable visual dysfunction due to chronic optic neuropathy. Each took Aimspro on an informed consent basis from one to three times weekly. Measures of color and distance acuity and visual evoked potentials were done immediately prior to the first injection, then one hour, one week and four to seven weeks thereafter. The investigators found significant improvement in color vision over the course of four to seven weeks of treatment, but noted that this kind of color testing is known to improve due to learning effects. The investigators underscored the need for a controlled trial to confirm these uncontrolled observations.

According to its Web site, the manufacturer is planning controlled clinical trials of Aimspro in several different conditions, including a study of bladder dysfunction in MS.

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