

Monitoring recovery from autoimmune disease with an interactive, Internet-based clinical trial based on a molecular model of chronic disease.

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Based on this author's experience on an NIH data, safety and monitoring board, we devised and conducted a phase II clinical study of a VDR-agonist, antibacterial therapy which demonstrated proof of concept of a novel biological description of the autoimmune disease process [1]. We collected evidence that restoring innate immune system competence will reverse the disease progression [2]. This multi-factorial therapy activates the Vitamin D Nuclear-Receptor, enabling the innate immune system to attack the intracellular microbiota which dysregulates Vitamin D metabolism. Additionally, it reduces elevated 1,25-dihydroxyvitamin-D and reduces co-morbid cognitive impairment [3]. Nurses who monitor the subject's progress are well-grounded in molecular science to help them accurately assess the effects of the recovery process. Instruction of subjects and their participating physicians occurs online. All communication is done in writing using a standard report form to facilitate accurate assessment and collect objective data. Ongoing, regular reports and rapid feedback by Nurses, ensures early detection of unexpected treatment effects. We describe the observational skills needed, the assessment techniques used and the limits/advantages of monitoring subjects using this format. As a result of the therapy subjects experienced diminishing relapse and remission of inflammatory symptoms [4]. Over 3-5 years this resulted in recovery from the disease process.

1. Marshall Trevor G *Bioessays* 2008 Feb; 30(2): 173-82
 2. Marshall TG et al *The Journal of the Interregional Clinical-Diagnostic Center, Kazan.* ISSN:1726-6149
 3. Mangin M. Abstract presentation Days of Molecular Medicine April 2008
 4. Marshall TG et al *Autoimmunity Reviews June 2004 Elsevier B.V.*
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