

## RESEARCH/CLINICAL UPDATE

March 9, 2007

**Keyword: Cannabis (Sativex)**  
**SECTION: TREATMENTS,**  
**INVESTIGATIONAL**

### **Patients in Cannabis-Based Drug Trial Reported Some Benefit for Relieving Spasticity in MS**

A six-week, placebo-controlled clinical trial of an oral spray drug derived from whole cannabis plants (Sativex<sup>®</sup> -- GW Pharmaceuticals, Salisbury, UK) involving 189 individuals with multiple sclerosis showed positive changes in a self-reported measurement of spasticity. Spasticity is a common and often painful symptom of MS that involves feelings of stiffness, tightness or sudden movements caused by a wide range of involuntary muscle spasms. Those using the active drug were more likely to report subjective feelings of benefit versus those on inactive placebo, but other outcomes including the more objective Ashcroft Score for spasticity did not show statistically significant benefit.

Study Details: All participants enrolled in the study had significant spasticity in at least two muscle groups and had failed to gain relief using approved therapies. Individuals were randomly divided into an active treatment group (124 people) and an inactive placebo group (65 people), staying on any current medications they were taking. Participants kept daily diaries recording their own assessment of their spasticity based on a 0 to 10 rating scale (where 0 is “no spasticity” and 10 is “worst ever spasticity”). The primary outcome of the trial was based on the adjusted mean change of this numerical rating scale of spasticity.

At the end of the six-week treatment period, 40% of those on active drug experienced at least a 30% reduction their self-assessed spasticity compared to 21.9% of those on inactive placebo. Those on active therapy were more likely to experience dizziness, impaired balance, attention disturbance and blurred vision. Six of those on active treatment and two on placebo withdrew because of adverse events. Any long-term adverse effects cannot be evaluated from this short study.

(MORE)

Sativex is a registered trademark of GW Pharmaceuticals

Conclusions: This is an additional short-term study that showed modest benefit from the viewpoint of the patient, but did not provide objective evidence of the benefit of Sativex. In order for any therapy to be recognized as an effective treatment, this kind of subjective reporting needs to be supported by carefully-gathered, objective evidence of safety and benefit. Unfortunately, it has proven difficult to do carefully controlled clinical trials of marijuana. One reason for this is that marijuana is psychoactive and tends to make people feel “high.” This means that people taking the active drug during a clinical trial usually become aware of it -- thus “unblinding” the study and possibly biasing results. In this study, there was no attempt to determine the effectiveness of the blinding methods used.

Conflicting results of previous research, coupled with the need for additional therapies to treat symptoms of MS, make it important that more research be done on the potential of marijuana and its derivatives. The National MS Society is funding a controlled study on the effectiveness of different forms of marijuana to treat spasticity in MS, using new technology to evaluate spasticity in an objective manner. The Society has also established a task force to examine the use of cannabis in MS to review what is currently known about its potential. This task force will make specific recommendations on the research that still needs to be done to answer pressing questions about the potential effectiveness and safety of marijuana and its derivatives in treating MS.

For more information about cannabis in MS, go to our Web site:

<http://www.nationalmssociety.org/Sourcebook-Marijuana.asp>

-- Research and Clinical Programs Department