



## Researchers review IBM best practices

The Cochrane Collaboration is an independent, non-profit, non-governmental organization made up of more than 37,000 volunteers in 130 countries. The collaboration was formed to organize medical research information in a systematic way to inform the choices that health professionals, patients, policy makers and others face in health interventions according to the principles of evidence-based medicine.

The group conducts systematic reviews of randomized controlled trials of health-care interventions, which it publishes in The Cochrane Library.

Neuromuscular specialists, including Drs. Michael Rose, Katherine Jones, Kevin Leong, Maggie Walter, James Miller, Marinos Dalakas, Ruth Brassington, and Robert Griggs, reviewed the evidence from clinical trials about the effects of drug treatments for inclusion body myositis (IBM). Their review did not include trials of exercise or management of swallowing difficulties, as these are subjects of other reviews. Researchers report on what they found:

The review included 10 trials (249 participants). One of these trials was completed but has not yet been published; seven trials compared treatment with placebo (inactive treatment): three were trials of intravenous immunoglobulin (IVIg), two of interferon beta-1a; and one each of oxandrolone, methotrexate, and arimoclomol (not yet published). Two additional trials compared methotrexate with combined immunosuppressive therapy and with an agent that destroys white blood cells (ATG); and with azathioprine. In these two trials, participants and investigators knew which treatment participants were receiving, which could have biased the results.

## Results and quality of the evidence

For the primary outcome, which was muscle strength, they were only able to combine the results for the two trials of IFN beta-1a therapy versus placebo. This treatment did not appear to offer a benefit in terms of muscle strength. Methotrexate also did not stop or retard loss of muscle strength when compared to placebo. Evidence from these trials was considered to be of moderate quality because the trials were too small to rule out a possible benefit for these drugs. For the other trials, the evidence was of very low quality. Three trials compared IVIg (combined in one trial with prednisone) to a placebo, but were unable to perform meta-analysis because the available data were not suitable. One trial of ATG combined with methotrexate versus methotrexate alone provided very low-quality evidence of an effect on muscle strength in favor of methotrexate plus ATG at 12 months. The other comparisons, of methotrexate versus placebo, oxandrolone versus placebo, azathioprine combined with methotrexate versus methotrexate alone, and arimoclomol versus placebo were reported in single trials that did not provide enough data for analysis of the effect on muscle strength.

Due to their small size and short duration, the trials studied were generally unable to give definitive answers as to whether the treatments tested were effective. All of the interventions studied had some adverse effects and are known to cause potentially serious adverse events. Larger trials of longer duration are needed, using robust ways of measuring the effects of treatments that are meaningful to people with IBM. Agreeing on common trial measurements will also make it easier to compare trial results and assess potential treatments.

The evidence is current to October 2014. The international researchers involved discussed their findings, as well as other strategies for managing IBM, in London on September 30, 2015. ●