

## **ARTHRITIS**

### **DOUBLE BLIND STUDY VERIFIES EFFECTIVENESS OF A NATURAL FORMULATION**

A double blind medical study confirms that Irena - a natural formulation comprising of Royal Jelly, Ginseng and Echinacea - is effective in the treatment of arthritis. It concludes that "Despite the short period of the study, 12 weeks, there have been improvements to virtually all the arthritic volunteers involved there is no doubt that every group (except the psoriatic) has benefited from the medication supplied during the trial.

"The effect of the formulation on pain produced the greatest overall improvement - a reduction by 18%." The reduction in pain levels is much greater for the formulation group and also steadier" and analysis of the results revealed that "not only was the reduction in pain large, it was fast, producing a greater than 10% fall in 4 weeks."

Despite a long history of arthritis - evidence of the disease has even been found in dinosaur bones - understanding the causes still eludes medical science. The symptoms, as any sufferer will attest include terrible pain, stiffness, swelling, reddening and or heat in affected joints. Local musculature may be involved and joint deformation may occur, especially for those suffering from rheumatoid arthritis.

Several types of arthritis have been identified the most common of which are:

- Rheumatoid - degenerative pain and inflammation of the joints often leading to stiffness.
- Osteo - wear and tear arthritis leading to loss of protective cartilage and pain. Sometimes occurs after injury.
- Ankylosing spondylitis - stiffening or fusion of the bones in the spine, although often it only affects the pelvis.
- Arthrogyposis - fibrous stiffening of joints.
- Psoriatic (chronic skin) disorder which can lead to a severe form of arthritis.

Until now, treatment consists of the alleviation of symptoms of the disease with drugs which can have serious and long term side effects. For example, non-steroidal anti-inflammatory drugs cause gastro-intestinal bleeding and ulcers - an on line trawl of medical publications produced 72 review articles alone, concerned solely with the side effects of these drugs!

The alternative conventional treatments are oral steroids, which have dreadful side effects including brittle bones, fluid retention, male pattern baldness and thinning of skin, or strong painkillers which produce a loss of alertness.

A new generation of NSAIDS is now being tested; however these are all geared towards alleviation of symptoms rather than actually treating the underlying condition. Whilst drug induced immuno-suppression with cyclosporine shows promise for sero-positive arthroses, this powerful drug can have serious side effects such as hypertension, hirsutism, loss of

appetite, tremors, swollen bleeding gums, and even an increased risk of cancers, in particular skin cancer.

### **What's the alternative?**

Against this pessimistic backdrop, it was felt that it was an opportune time to embark upon a double blind medical trial into the efficacy of a completely natural compound Irena, developed nine years ago by a team of biochemists, homeopaths and herbalists headed by Dr. Emile Coufalik. Irena in all those years of experience has had no reported adverse effects.

The constituents of the Irena formulation are a finely balanced compound of Royal Jelly, Ginseng, Echinacea, Serenoa Serrulata, Capsicum Minimum and honey which act homeopathically - some to alleviate symptoms, whilst others are there to potentise. In fact, the addition of the Echinacea and the Ginseng potentise the Royal Jelly ten fold and have an equally relevant role to play in their own rights since they are responsible for the alleviation of symptoms in their own rights.

Sufficient anecdotal evidence attesting to the formulations efficacy, effectiveness and safety had been accrued over a period of four years of field trials (and 15 years of preceding research) to merit serious investigation into its alleviation of the symptoms associated with arthritis. (Post trial corroboration by Professor Tony Vas showed that testimonial proof makes valuable research material).

As a consequence a trial protocol was developed by a team comprising a doctor, nurse, and statistician and 200 volunteers were recruited once they could prove a positive medical diagnosis of arthritis. The volunteers were randomly allocated to a group taking either a daily dose of 10 ml of the Irena formulation or a placebo for a three month period.

## **Results**

### **Pain**

Analysis of the results showed that "The effect of the formulation on pain produced the greatest overall improvement - a reduction by 18%."

Interestingly, it also revealed that "The reduction in pain levels is much greater for the formulation group and also steadier."

And thirdly it showed that "not only was the reduction in pain large, it was also fast, producing a greater than 10% fall in pain levels within 4 weeks with minor fluctuations thereafter. For most people pain is probably one of the most significant symptoms of arthritis. Severity of pain on movement will restrict the degree of movement tolerated, leading to stiffening and

therefore further deterioration. This becomes a downward spiral, with very often depression occurring as the quality of life deteriorates and mental and physical energy declines."

Pain is believed to occur because of the stimulation of nerve endings by mechanical irritation or inflammation from pressure of entrapped nerves or from muscle spasm. The Ginseng in the formula contains a saponin, ginsenoside Rf, which has been shown to act as a powerful opiate, mimicking the action of opiates by N-channel inhibition. This prevents Ca<sup>2+</sup> evoked neurotransmitter release from sensory neurones and therefore no pain is transmitted.

Meanwhile the effect of Royal Jelly on arthritics is perhaps better known. For centuries the Chinese have harnessed the natural analgesic effect of Royal Jelly and commonly directed it into affected joints. In the UK as early as 1963, Barton - Wright - Elliot found that Royal Jelly administered to arthritics raised levels of Pantothenic acid (Vitamin B5) in 70% of their rheumatoid patients who subsequently experienced increased mobility and a fall in the eosinophil sedimentation rate, indicative of a reduction in inflammation. The improvement continued as long as daily administration was maintained.

Thirdly evidence exists that *Serenoa Serrulata* within the formulation has anti-inflammatory properties whilst clinical trials have confirmed that *Echinacea* is used to great effect to counter chronic inflammatory diseases which result from low grade sub clinical infections, it is also effective in stimulating the immune system and because of this a homeopathic distillate is included in the formulation. Finally *Capsicum* (cayenne) has antiseptic and counter-irritant properties and is known to reduce pain.

The researchers found that:

**Patients taking Irena whether with rheumatoid or osteoarthritis reported significant reductions in pain levels after eight weeks of treatment. It would seem that the improvement associated with taking Irena was significant"**

### **Speed**

Half the volunteers were over 61 years old and yet the response was not only great but also rapid, producing a reduction in the first 4 weeks that was maintained overall and continued to the end of the study." Considering that the majority of the group had been suffering from arthritis from between 6 to 15 years, this rapid response is particularly exciting.

### **Mobility**

There was a positive increase in mobility with a gain of 20% overall - the greatest improvement was experienced by the Ankylosing Spondylitis group on the formulation who saw a rise of 17%.

### **Other Observations**

"Arthritic induced fatigue in rheumatoid arthritis is inversely proportional to the severity of the inflammatory process many volunteers reported an upsurge in energy...both Royal Jelly and Ginseng have been shown to improve alertness, relaxation, appetite, vitality and depression. Combined with a reduction in the debilitating pain that arthritics experience accounts for the volunteer reports of increased energy and well being and is a good example of how all the Irena constituents act in synergy."

### **Conclusion**

**"The trial revealed that the Irena formulation proved to contain active ingredients which provided beneficial responses well beyond those that could be expected from a placebo effect." Further investigation into both the physiological changes being made and the sustainability of the positive responses observed would be well worth undertaking, *especially* in the light of the fact that there is currently no safe, efficient or effective drug available.**