

# FOCUS ON RESEARCH

## TITLE

### **RANDOMISED STUDY OF EMBOLISATION AND SURGICAL TREATMENT FOR UTERINE FIBROIDS (REST)**

#### **Researchers**

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#### **Aim**

To compare a new technique (uterine artery embolisation (UAE)), which involves blocking the uterine arteries by an injectable agent, with surgery (hysterectomy or removal of fibroids) in patients with symptomatic fibroids who would ordinarily receive surgical treatment.

#### **Project Outline/Methodology**

A randomised controlled trial involving all but two Scottish Health Boards plus two English centres. Randomisation used a 2 : 1 allocation of patients to UAE and surgery respectively. 157 subjects were randomised over a 30 month period. Quality of life measured at 12 months was the primary outcome measure. Secondary outcome measures included morbidity, pain scores, time to achieve various lifestyle events, hospital stay and reintervention rates.

#### **Key Results**

95% of patients underwent their allotted treatment (UAE 101, hysterectomy 40, myomectomy 8). There was no statistical significant difference in quality of life at 1 year. The length of hospital stay was significantly shorter in those having UAE compared with surgery. The time to performing routine tasks was significantly shorter in the UAE group. Symptom scores were significantly better in the surgical arm at all time points. Ten (9%) of patients in the UAE arm required further invasive treatment for symptom control. At 1 year women randomised to UAE had a 4% probability of having a repeat UAE and a 6% chance of a hysterectomy. There were 33 (31%) serious adverse events (SAE's) in the UAE arm and 9 (18%) in the surgical arm at latest follow up (maximum 56 months). Economic analysis showed a significant difference in cost (UAE £1757 vs £2702 surgery).

#### **Conclusions**

Both surgery and UAE provide a successful outcome for a majority of women with symptomatic fibroids. There was no difference in the primary outcome

measure (QoL) at 1 year. Short term follow up of those having UAE showed a significantly more rapid recovery period but significantly poorer symptom control compared to surgery. Complications after surgery usually occurred in the early post-operative period whereas some of those occurring after UAE did so after a prolonged period of time. The study was not big enough to show the effect of UAE on fertility or pregnancy.

#### **What does this study add to the field?**

This is the first RCT to report 12 month outcomes comparing UAE with the traditional surgical remedies. There was no difference in QoL between the two groups at 1 year.

#### **Implications for Practice or Policy**

UAE should be considered for patients as an alternative to surgery for symptomatic fibroids. The advantage of faster recovery following UAE must be weighed against the need for further treatment in a minority of patients, long term complications and an unknown effect on pregnancy. Data from this study will provide the gynaecologist, radiologist, primary health care practitioner and patient with more information to help decide the appropriate treatment for individual patients with fibroids.

#### **Where to next?**

More research is needed on the long term outcome of UAE in regard to recurrence of both fibroids and symptoms requiring further treatment. Also, an RCT of UAE and myomectomy would examine issues of fertility appropriately since only observational data are available at present

#### **Further details from:**

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