



Uterine Fibroid Embolisation. The FEMME Trial!

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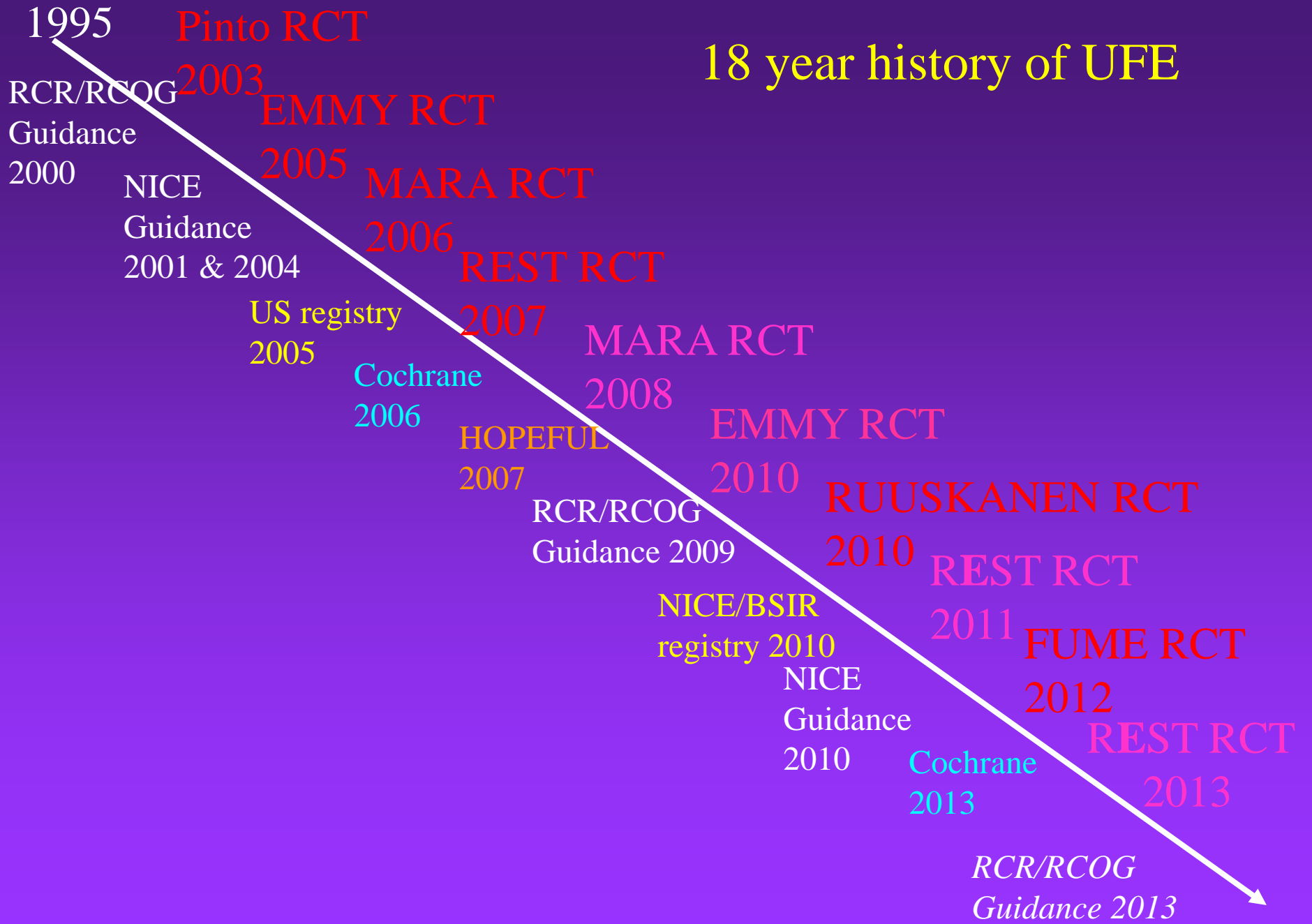




FEMME

A randomised trial of treating **F**ibroids with **E**mbolisation or **M**yomectomy to **M**easure the **E**ffect on quality of life among women wishing to avoid hysterectomy

18 year history of UFE

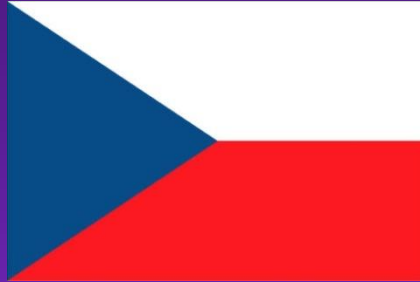


2013

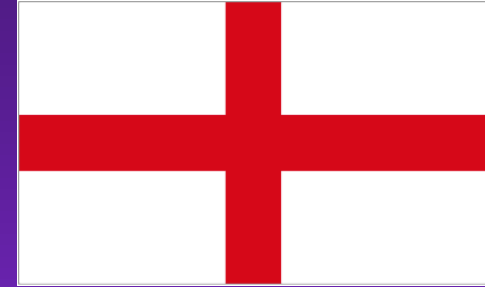
Pinto
n=57



Czech
n=121



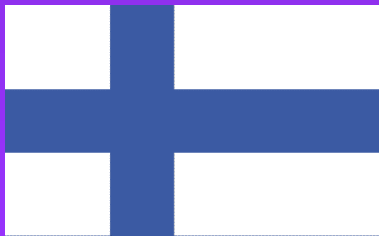
St George's FUME
n=163



Randomised trials

n=732

Ruuskanen
n=57



REST
n=157



EMMY
n=177





4 RCTs

Pinto, Ruuskinen, REST and EMMY

- Surgical arm- hysterectomy
- Shorter hospital stay with UAE
- SFQOL significantly improved equally
- More reinterventions for fibroid symptoms after UAE
- More major complications following hysterectomy
- More minor, delayed complications post UAE
- UAE cost neutral compared with hysterectomy despite repeat interventions



RCT-Mara

UAE for Fibroids

- RCT 121 women UAE vs Myo (*Mara et al CVIR 2006,2008*)

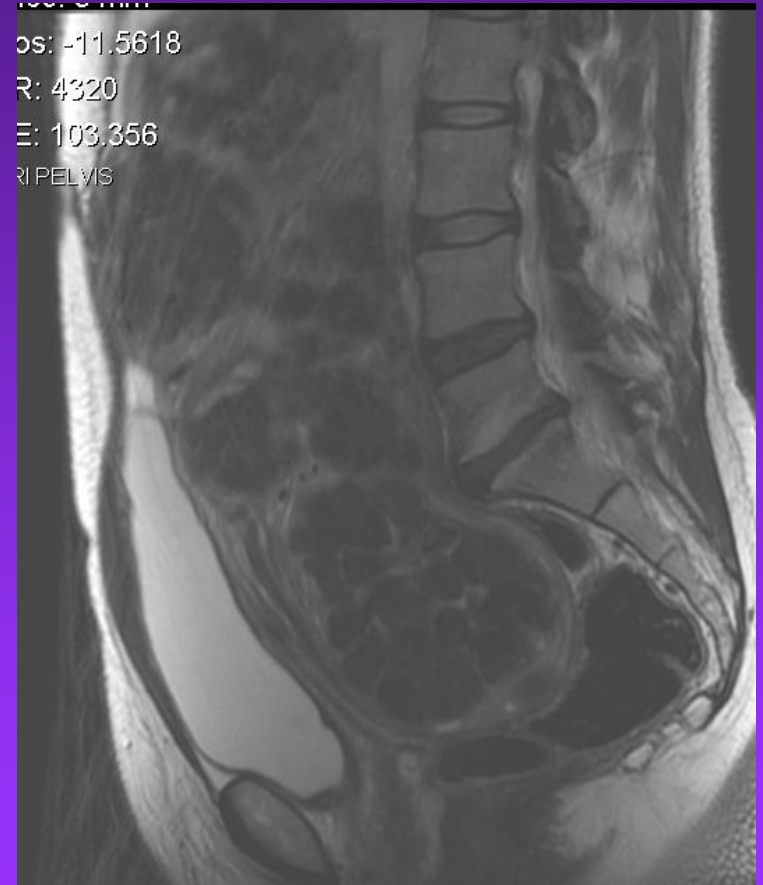
	UAE	MYO
Total treated	58	63 (42 lap)
Single myoma (%)	67	64
>5 fibroids (%)	26	33

At 2 yrs, no difference in symptomatic effectiveness, post procedural FSH levels, reintervention rates, or complications.



RCT- FUME

- 82 UAE vs 81 abdominal myomectomy
- Shorter hospital stay
- SFQOL significantly improved in both
- Major complications 3% UAE vs 8% myo
- Reinterventions at 2 years 14% UAE vs 3% myo



(Manyonda et al CVIR 2012)



Uterine sparing procedures

Myomectomy



23%

Re-intervention
5 years



30%

Re-intervention
7 years

Endometrial ablation



25%

Re-intervention
5 years

UAE



28-32%

Re-intervention
5 years



Uterine artery embolisation for fibroids

This document replaces previous guidance on uterine artery embolisation for the treatment of fibroids (interventional procedure guidance 94).

1 Guidance

- 1.1 Current evidence on uterine artery embolisation (UAE) for fibroids shows that the procedure is efficacious for symptom relief in the short and medium term for a substantial proportion of patients. There are no major safety concerns. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance and audit.
- 1.2 During the consent process patients should be informed, in particular, that symptom relief may not be achieved in some women, that symptoms may return and that further procedures may therefore be required. Patients contemplating pregnancy should be informed that the effects of the procedure on fertility and on pregnancy are uncertain.
- 1.3 Patient selection should be carried out by a multidisciplinary team, including a gynaecologist and an interventional radiologist.
- 1.4 NICE encourages further research into the effects of UAE compared with other procedures to treat fibroids, particularly for women wishing to maintain or improve their fertility.

UK. They may be asymptomatic or may cause symptoms such as abnormal uterine bleeding, urinary incontinence, a feeling of pelvic pressure, or pain. They may also be associated with reproductive problems such as infertility and miscarriage.

- 2.1.3 Asymptomatic fibroids require no treatment. Treatments for symptomatic fibroids include hysterectomy and myomectomy.

2.2 Outline of the procedure

- 2.2.1 The aim of UAE for fibroids is to offer a less invasive alternative to hysterectomy or myomectomy with preservation of the uterus, and a faster recovery time. Uterine artery embolisation is sometimes used before a planned myomectomy.
- 2.2.2 With the patient under conscious sedation and local anaesthesia, a catheter is inserted into the femoral artery (bilateral catheters are sometimes used). Fluoroscopic guidance is used to manipulate the catheter into the uterine artery. Small embolisation particles are injected through the catheter into the arteries supplying the fibroids, with the aim of causing thrombosis and consequent fibroid infarction.



Research Questions

- Recurrence rates of UAE compared with all types of myomectomy



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- Recurrence rates of UAE compared with all types of myomectomy
- Complication rates & outcomes of UAE vs all types of myomectomy



Research Questions

- Recurrence rates of UAE compared with all types of myomectomy
- Complication rates & outcomes of UAE vs all types of myomectomy
- Effect on fertility



Guidelines

- *As a measure of precaution women presenting with fibroids who have a desire for children are not generally eligible for embolisation*



Guidelines

- *As a measure of precaution women presenting with fibroids who have a desire for children are not generally eligible for embolisation*

Although the same procedure is used for women with PPH since late 1970's

ACOG Committee Opinion: Uterine Artery Embolisation (2004)



UAE & Pregnancy

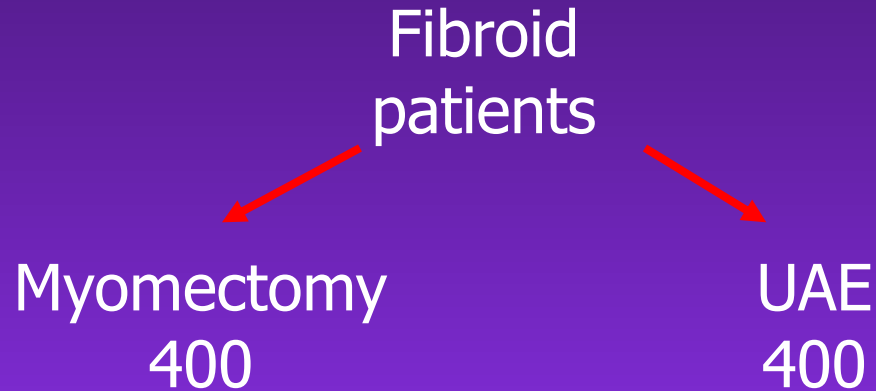
- Systematic review of 21 studies

“pregnancy rates following UAE are comparable to age adjusted rates in the general population”

“pregnancy complication rates were similar to patients with untreated fibroids, although a few studies have reported higher miscarriage rates following UAE”



FEMME trial: A UK randomised trial of treating Fibroids with Embolisation or Myomectomy to Measure Effectiveness



QoL
Ovarian reserve
Cost
Pregnancy outcomes



FEMME Trial

- Other than the randomisation to myomectomy or UAE, treatment is normal practice
- If randomised to myomectomy this can be of any type including laparoscopic, hysteroscopic or open laparotomy
- If randomised to UAE this is normal practice



FEMME Trial



FEMME Newsletter

May 2013



It's a Boy!

We are delighted to announce the birth of the first baby born to a patient in the FEMME trial! The baby boy was born on 23rd May 2013 to a patient randomised at a centre in Scotland who underwent a UAE prior to conceiving. Both mother and baby are doing well....congratulations!

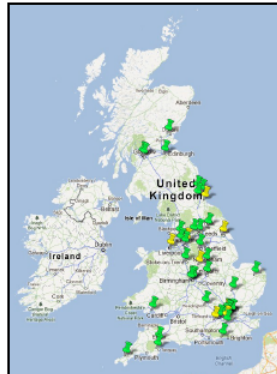
Welcome!

Welcome to the latest centres to join FEMME:

- **Queen's Hospital, Barking, Havering and Redbridge**
Principal Investigator: Mr Leye Thompson
Approval granted: 7th May 2013
- **Royal Free Hospital, London**
(Acting) Principal Investigator: Mr Ioannis Tsimpanakos
Approval granted: 21st May 2013

FEMME now has local approval at 33 sites!

We would also like to welcome two new members to the FEMME Trial Management Group! Mr Brian Brady, Consultant Gynaecologist joins us from the Royal Infirmary of Edinburgh and Mr Justin Clark, Consultant Obstetrician and Gynaecologist joins us from Birmingham Women's Hospital



Approved



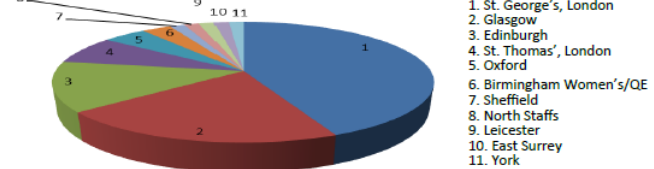
Centres pending approval



Patient recruitment

- Up to April 1022 patients have been reported as being screened
- 67 patients have been randomised to date

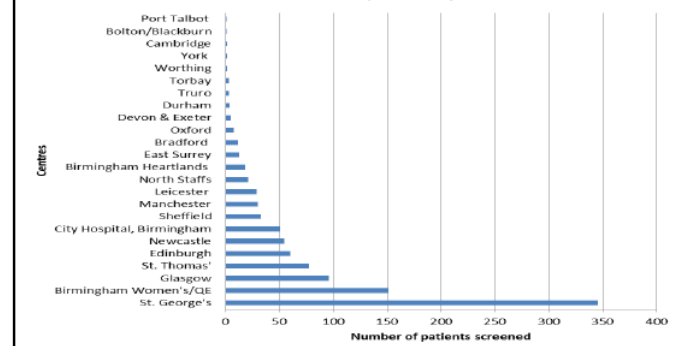
Patients randomised up to 30th May



Patients randomised up to 30th May

Centre	Patients Recruited
1st - St. George's Hospital, London	29
2nd - Glasgow Royal Infirmary	14
3rd - Royal Infirmary of Edinburgh	9
St. Thomas' Hospital, London	5
John Radcliffe Hospital, Oxford	3
Birmingham Women's Hospital/Birmingham QE	2
Royal Hallamshire Hospital, Sheffield	1
City General Hospital, North Staffordshire	1
Leicester General Hospital	1
East Surrey Hospital (Redhill)	1
York Hospital	1
Total	67

Patients screened up to 30th April





FEMME Trial



<http://www.birmingham.ac.uk/femme>



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Thankyou



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