Randomised Trial of Bead Block® vs EmboSphere® for UFE

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A double-arm (non-inferiority) 44-patient study to assess the performance of Bead Block® in the treatment of uterine fibroids by embolisation with respect to clinical and imaging outcome with comparison of primary safety endpoints to EmboSphere®.

**Outcome Measures**

**Primary Endpoint**
Change in fibroid devascularisation as seen at contrast-enhanced MRI (CEMRI) performed several days after uterine fibroid embolisation (UFE) and three months following the UFE: Comparison between Bead Block® and EmboSphere®.

**Secondary Endpoint**
Mean difference of change in fibroid devascularisation CEMRI performed several days after UFE and six months following the UFE: Comparison between Bead Block® and EmboSphere®.

Assess the change from baseline in uterine fibroid symptom quality of life [UFS-QOL]) at three, six and twelve months (+/-15 days) follow up: Comparison between Bead Block® and EmboSphere®.

**Study Design**

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- Best protocol for each embolic
  - Bead Block® – start with 700-900µm
  - EmboSphere® – start with 500-700µm, unless ovarian artery seen
  - Upsize if necessary in both arms

**Embolisation Endpoints**
- New filling of ovarian arteries or cross-uterine collaterals
- Retrograde flow around catheter tip
- “Plumping” of artery with injection
- No further filling of ascending branch

**MRI Grading**
- Pre-UFE perfusion scored at 10
  - Global fibroid burden, not just dominant fibroid
- Follow-up perfusion scored 1-10
  - 1 = 100% infarction all visible fibroids
  - 1-2 = 90 to <100% infarction
  - 3-4 = 70 to <90% infarction
  - 5+ = Failure <70% infarction

**Trial meets good evidence criteria demanded when assessing medical devices**
Spies JB. J Vasc Interv Radiol 2009; 20:567-70
- Well–defined inclusion/exclusion criteria
- Adequate sample size/power analysis
- Randomisation by independent third party
- Blinded to patient and image reviewer
- Identical care and follow-up
- Intention to treat analysis
- Blinded imaging assessment
- Clear endpoint assessment
- UFS-QOL
- Enhanced MRI
- Reporting
No statistical difference in fibroid perfusion over six months

No statistical difference in proportional change in fibroid or uterine volume
Important Information

Indications:
• In Europe, Bead Block® is intended to be used for the embolisation of hypervascular tumours, including uterine fibroids and arteriovenous malformations (AVMs)
• In the USA, Bead Block® is not cleared by the FDA for uterine fibroid embolisation and is intended to be used for the embolisation of hypervascular tumours and arteriovenous malformations (AVMs) only

Potential Complications:
1. Undesirable reflux or passage of Bead Block® into normal arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds
2. Non-target embolisation
3. Pulmonary embolisation
4. Ischaemia at an undesirable location
5. Capillary bed saturation and tissue damage
6. Ischaemic stroke or ischaemic infarction
7. Vessel or lesion rupture and haemorrhage
8. Neurological deficits including cranial nerve palsies
9. Vasospasm
10. Death
11. Recanalisation
12. Foreign body reactions necessitating medical intervention
13. Infection necessitating medical intervention
14. Oedema formation at the tip of the catheter and subsequent dislodgement

UFE-Specific Potential Complications:
Potential post-procedure complications include:
1. Abdominal pain
2. Discomfort
3. Fever
4. Nausea
5. Constipation
6. Premature ovarian failure (ie menopause)
7. Amenorrhoea
8. Infection of the pelvic region
9. Uterine/ovarian necrosis
10. Phlebitis
11. Deep vein thrombosis with or without pulmonary embolism
12. Vaginal discharge
13. Tissue passage, fibroid sloughing, or fibroid expulsion post-UFE
14. Post-UFE intervention to remove necrotic fibroid tissue
15. Vagal reaction
16. Transient hypertensive episode
17. Hysterectomy

Results: UFS-QOL

Equivalence in QOL scores in both arms

Conclusion

This study shows that Bead Block® and EmboSphere® perform equivalently with regards to the rate of fibroid devascularisations, volume reduction and QOL.

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