Name of Sponsor/Company: **UoE/NHS Lothian**	Individual Study Table Referring to Part of the Dossier	*(For National Authority Use only)*
Name of Finished Product:	Volume:	
Name of Active Ingredient:	Page:	

Title of Study:

Abdominal Aortic Aneurysm Growth Predicted by Uptake of Ultrasmall Supermagnetic Particles of Iron Oxide: a pilot study

Investigators: **Richards J, Semple S, MacGillivray T, Gray C, Langrish J, Williams M, Dweck M, Wallace W, McKillop G, Chalmers R, Garden O, Newby D.**

Study centre(s): **Royal Infirmary Edinburgh**

Publication (reference):

Circulation: Cardiovascular Imaging 2011 May 4(3) 274-81

Studied period (years): (date of first enrolment) **Aug 2009** (date of last completed) **Dec 2009**	Phase of development:

Objectives:

Using MRI to assess whether areas of cellular inflammation correlated with the rate of AAA expansion.

Methodology:

Recruited from a surveillance clinic and imaged using a 3-T MRI scanner before and 24-36 hours after administration of ultrasmall superparamagnetic particles of USPIO.

Number of patients (planned and analysed):

29 recruited

Diagnosis and main criteria for inclusion:

AAA with a diameter 4.0cm on USS. Exclusion: under 40, pregnant, active systemic inflammatory or malignant disease, renal dysfunction, hepatic cirrhosis, contraindication to MRI

Test product, dose and mode of administration, batch number:

IV USPIO 2.6mg/kg

Duration of treatment:

30 minutes

Reference therapy, dose and mode of administration, batch number:

NA

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Criteria for evaluation:
Efficacy:

Safety:

Statistical methods:

The data were normally distributed. Continuous data were compared with 1-way ANOVA with Tukey post test comparison (Minitab) and categorical data were analysed using the x2 test with cross tabulation (SPSS). Statistical significance was taken as 2-sided P,0.05.

SUMMARY - CONCLUSIONS

EFFICACY RESULTS:

CONCLUSION: Uptake of USPIO in abdominal aneurysms identifies cellular inflammation and appears to distinguish those patients with more rapidly progressive abdominal aortic aneurysm expansion.

SAFETY RESULTS: There was no significant adverse events noted.

CONCLUSION: Uptake of USPIO in abdominal aneurysms identifies cellular inflammation and appears to distinguish those patients with more rapidly progressive abdominal aortic aneurysm expansion.

Date of the report: 20 Mar 17