SaFaRI: sacral nerve stimulation versus the Fenix® magnetic sphincter augmentation for adult faecal incontinence: a randomised investigation

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Dear Editor:

We read with interest the SaFaRI Clinical Study Protocol recently published online in the International J. of Colorectal Disease by Williams et al. [1]. This multicentre randomised clinical trial (RCT) (trial registration: ISRCTN 16077538) granted by the UK National Institute of Health Research aims to compare the Fenix® magnetic anal reinforcement device to sacral nerve stimulation (SNS) in the treatment of refractory faecal incontinence (FI).

This trial is most welcome in the difficult-to-assess field of FI surgical strategy. The SaFaRI trial is based on similar grounds of the trial currently underway in France under the auspices of the Ministry of Health in a specially granted programme “Soutien aux technologies innovantes, couteuses ou non” (STIC). This multicentre, randomised, interventional, open-label trial identified as MOS STIC (for Magnets Or Stimulation) has been registered in ClinicalTrials.gov under the reference NCT01920607 (appeared on August 8, 2013) with a first implantation of a randomised patient in December 15, 2013.

The MOS STIC, a “non-inferiority” trial has the following hypothesis: “the Fenix® magnetic anal reinforcement device is clinically as effective as SNS, but more cost-effective in managing severe FI”. Although of a very similar design as compared to SaFaRI, MOS STIC has some perceptible differences such as less investigating centres (*n* 10) as such a trial

involves only highly specialised units, a lower number of patients (*n* 156) for a shorter study duration (2 years).

In line with the trial hypothesis, to demonstrate efficiency, the selected primary study endpoint is a ≥ 50 % reduction in the average number of incontinence episodes per week as recorded in a 3-week bowel diary. This endpoint is measured at 6 months, a delay long enough to appreciate the treatment effect and not at 18 months as for SaFaRI. As well to determine the cost-effectiveness of Fenix® in comparison with that of SNS, secondary trial objectives include a detailed medico-economic study to record individual medical benefit, the benefits to the community, and the costs associated with the use of two treatment modalities.

Recruitment of patients into MOS STIC trial will end in May 2016 as a request from the sponsor and results will be disclosed soon after.

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on behalf of the “MOS STIC” investigational group.

Reference

1. Williams AE, Croft J, Napp V et al (2016) SaFaRI: sacral nerve stimulation versus the FENIX™ magnetic sphincter augmentation for adult faecal incontinence: a randomised investigation. Int J Color Dis. doi:10.1007/s00384-015-2492-3

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