



Scottish Pelvic Floor Network

Dr. Mohamed Abdel-fattah, FRCOG

Senior Lecturer/ Consultant Gynaecologist
Sub-specialist in Urogynaecology & Pelvic Floor Reconstruction

Chairman - Scottish Pelvic Floor Network (SPFN)"

Obstetrics & Gynaecology
Division of Applied Health Sciences
School of Medicine & Dentistry
Aberdeen Maternity Hospital
Cornhill Road
Aberdeen AB25 2ZD
Scotland, United Kingdom
Tel: (+44) 01224 438424
Email: m.abdelfattah@abdn.ac.uk

Mr. Alex Neil
Health Minister – Scottish Government

Date: 17th June 2014

Dear Mr. Neil

We were surprised to hear from the media, without any prior notification in the SLWG which was convened at your instruction, of the decision to suspend trans-vaginal mesh (TVM) & mid-urethral synthetic slings (TVT) in Scotland pending independent review and the European Commission investigation.

Whilst we appreciate that you must have considered this decision carefully, this decision, if we don't act quickly, will have a significant negative impact on medical research in Scotland, which is the most important tool for improving healthcare in any health service. Scotland is currently leading the UK in 2 large multicentre studies, funded by NIHR for a total of £4 million and running in over 40 units in UK. As all Scotland-led clinical trials, patient-reported outcomes and experience are the primary outcomes assessed in these large clinical trials:

- (A) The SIMS study: comparing the standard TVT procedures for urinary incontinence with a shorter version tape, known as a mini-sling with 50% less mesh volume and can be easily tolerated under local anesthesia using less invasive surgery;
- (B) The VUE study: investigates the best treatment of uterine (womb) prolapse and whether hysterectomy is required, and

These 2 large and credible research projects can be negatively impacted by the decision of suspension and consequently we may never be able to reach an answer for the clinical dilemmas addressed by the projects.

May we ask the health minister to exempt "credible medical research" from the suspension decision? Credible research can easily be defined as those studies on the NHS portfolio. These studies were subject to rigorous independent review are ethically approved and funded by public money and moreover they are regularly monitored by NHS R&D. Women are voluntarily joining these studies after adequate counselling and signing of special consent forms.

The current Scottish government has announced in multiple occasions its support for high quality research and vowed to support it in Independent Scotland dossier. The position of Scotland as a leader of medical research with large funding bodies such as NIHR and research council can be jeopardized if we don't meet our obligations in leading the above trials. ***Hence we ask the health minister to exempt***

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"credible medical research" from the suspension decision and vow to support such research in NHS Scotland.

We are happy to discuss further as you see appropriate and present the research projects to you or to the CMO if requested

Look forward to hearing from you
Best Wishes

Mohamed Abdel-fattah, Chief Investigator SIMS study
Charis Glazener, Chief Investigator VUE study
John Norrie, Director of CHaRT clinical trials unit – University of Aberdeen/CSO
Chis Bain, Co-investigator VUE study
Kevin Cooper, Co-investigator VUE study and Co-Chief-investigator HEALTH Study and PREMPPT study