Final Research Report

Study title: A study to compare the effectiveness and morbidity of Alkalinized Intravesical Lidocaine vs Lidocaine gel in achieving anaesthesia prior to intravesical Botulinum toxin A (BTX) injections

REC reference: 10/MRE09/34
Protocol number: CRU01-AY1
EudraCT number: 2010-018611-15
IRAS project ID: 44305

The above study concluded on 28 February 2013. Recruitment achieved the number required by the pre-determined power calculation of 54 patients. A summary of the study is given below:

Objectives
To assess the efficacy and morbidity of alkalinised lidocaine solution compared to standard lidocaine gel for anaesthesia prior to intra-vesical botulinum toxin (BoNTA) injections in a statistically powered randomised controlled trial.
Comment – achieved

Results

- Recruitment was completed in December 2012. Of 60 randomised patients 54 received the allocated intervention and were analysed.
- Mean pain score in the AL group was 17.11mm (95% CI 8.65-25.57mm) and in the LG group was 19.53mm (95% CI 13.03-26.03mm). At 80% power and at a significance level of 0.05 there was no significant difference between the groups.
- Cost of interventional medication in the AL group was almost double that of the LG group.
- No adverse events were attributable to the local anaesthetic instillation in either group.

Conclusion
Alkalinised lidocaine solution is not superior to lidocaine gel in achieving anaesthesia prior to intravesical botulinum toxin injections, and the higher cost precludes its use over lidocaine gel for anaesthesia prior to intravesical procedures.

The results of the study have been submitted for publication to the BJUI (a copy of the submission document is attached). The results have also been presented in abstract/poster form to the United Kingdom Continence Society on 17-19 April 2013, and is due to be presented at the British Association of Urological Surgeons (BAUS) annual meeting in June 2013.

Sincerely,