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EVALUATION OF A NEW ELECTROSTIM TECHNOLOGY FOR THE TREATMENT OF URINARY INCONTINENCE IN WOMEN: A RANDOMISED CONTROLLED TRIAL

Hypothesis / aims of study

Neuromuscular electrical stimulation for the treatment of urinary incontinence is currently limited in the main to the use of therapist supervised devices, delivering uniform frequency stimulation patterns and by the availability of only rigid vaginal electrodes leading to discomfort in use. Femeda, a UK based company and scientists at the University of Manchester, UK have attempted to address these limitations. This study describes the evaluation of a self contained ,fully automated, disposable device (Femestim), with application similar to that of a tampon. The device comprising of an expandable foam electrode contained within an applicator effectively delivers a mixed frequency stimulation regimen comprising low (2Hz), intermediate, (30Hz) and high (in the form of a doublet) frequency stimulation delivered over a 30minute period (international patent publication WO98/47357). This abstract describes a rigorously controlled randomised trial that tests the null hypothesis that there will be no difference in outcome between women receiving standard written, unsupervised pelvic floor muscle exercise information compared to women who receive standard information plus the new Femestim device combined.

Study design, materials and methods

This study was undertaken to ICH GCP standards in the Manchester Wellcome Trust Clinical Research Facility. Ethical approval was granted by Sheffield Research Ethics Committee (06/Q2308/134). The study was powered (64 women per group) to detect a 3 point (common standard deviation of 6) between group difference on the ICIQ-UI (scale of 0-21) with 80% power at a 5% level of significance. Women with urinary incontinence were recruited via a process of self referral through adverts placed in local newspapers and on local radio to reflect future practice. All women were supplied with the same exercise sheet on how to correctly perform pelvic floor muscle exercises (obtained from the Continence Foundation [UK] – now the Bladder & Bowel Foundation). They were asked to follow these instructions during the first four weeks baseline assessment component of the trial. Women were then randomly allocated to one of two treatment groups by a computer generated randomisation list. Those women randomly allocated to the control group were asked to continue with the Continence Foundation exercise sheet approach for a further twelve weeks. The women randomly allocated to the stimulation group were also asked to continue with the exercise approach but in addition were supplied with enough single use disposable Femestim products to last them for twelve weeks of stimulation. Devices were then used for 30mins per day on a daily basis (except during menstruation). Each device was programmed to switch on automatically on insertion into the vagina, gradually automatically increase the intensity of stimulation to a therapeutic level and to switch off automatically after 30mins. Pre and post twelve weeks treatment, questionnaires assessing incontinence (ICIQ-UI), effect on sex life (ICIQ FLUTSex), global impression of severity and improvement and overall impression of the treatment were completed.

Results

Femestim plus exercise produced significantly better outcome when compared to unsupervised exercise alone. This amounted to 50% improvement for the Femestim group compared to 25% for the exercise alone group in terms of overall ICIQ-UI score ($p=0.05$), 67% vs 33% in terms of leak frequency ($p=0.029$) and 50% vs 33% in terms of leak interference with life ($p=0.032$). This translates to a change in frequency of leakage from once per day to once per week for the Femestim group. In terms of sexual activity it was apparent that in the majority of women their incontinence did not spoil or cause discomfort during sex. Women did however describe their incontinence as bothersome during sex. This improved for both groups though to a statistically significantly ($p=0.026$) greater extent in the Femestim group. Both groups of women described a reduction in severity of symptoms post treatment ($p<0.000$) though on average the number of women describing their condition as mild or normal post treatment was greater for the stimulation group (84.3%) than for the exercise only group (69.6%). Both groups described a similar degree of exercise participation ($p>0.05$) varying from nothing to three times daily. Women generally were enthusiastic about using the Femestim device, found it easy and comfortable to use and described moderate to strong contraction of the pelvic floor.

Interpretation of results

This trial demonstrates that the Femestim device is a highly successful product for the treatment of urinary incontinence when combined with pelvic floor muscle exercises and produces statistically significant superior results to unsupervised pelvic floor muscle exercises alone. Furthermore, there are no apparent adverse incidents associated with using the device. The device is generally easy and comfortable to use and facilitates contraction of the pelvic floor independent of volitional control. The mechanism of action is therefore likely to be due to re-education of pelvic floor function through a stimulation induced contraction. The product is now moving towards commercialisation with launch anticipated towards the end of 2010.

Concluding message

Femestim is a new and exciting disposable electrostim device that when used in combination with pelvic floor muscle exercises results in significant improvement in symptoms associated with urinary incontinence.

Specify source of funding or grant	**Femeda**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**

Specify Name of Ethics Committee	**Sheffield Research Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**