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SAFETY AND PERFORMANCE OF A WIRELESS IMPLANTABLE TIBIAL NERVE STIMULATOR DEVICE FOR THE TREATMENT OF PATIENTS WITH OVERACTIVE BLADDER (OAB)

Hypothesis / aims of study

This novel study evaluated the safety and performance of the newly developed wireless tibial neurostimulator, intended for home care use, for the treatment of patients with OAB.

OAB affects millions of people worldwide with neuromodulation offering a minimally invasive and reversible treatment option for patients who have failed first-line therapy. Multiple neuroanatomical pathways have been described for neuromodulation including the S3 nerve root, pudendal nerve and tibial nerve (1), with limited and preliminary publications on implantable tibial nerve stimulators (2,3). A novel peripheral tibial neurostimulator (BlueWind Medical Ltd.) for the treatment of OAB was recently developed. The system composed of an implant, which is wirelessly powered by an external control unit (ECU) that controls the therapeutic parameters and is worn by the patient during treatment at home. A Physician Programmer is used to remotely set individual stimulation parameters for each patient to optimize therapeutic outcome (Figure 1).

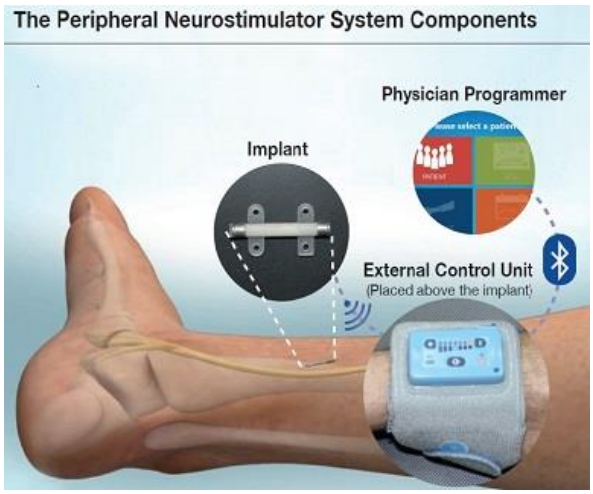

Figure 1: The wireless implantable neurostimulator components including the implant, External Control Unit (ECU) and the Physician Programmer.

Study design, materials and methods

A prospective self-controlled multi-centered study, with a period of 6 months follow up post system activation was conducted in 4 European sites. Two patient populations were enrolled in the study: patients with no previous treatment with percutaneous tibial nerve stimulation and patients who have been previously treated with percutaneous tibial nerve stimulation. In a minimally invasive procedure of about 30 min, the implant was secured close to the tibial neurovascular bundle approximately 5 cm proximally to the medial malleolus. The endpoints of the study were to determine incidence of serious adverse events and to assess the improvement in OAB symptoms at 6 months post activation as compared to baseline. Data is being collected via voiding diaries, quality of life questionnaire, OAB-q, and recording of adverse events.

Results

A total of 36 subjects have been implanted with the tibial neurostimulator. The Study cohort consists of 5 males and 31 females, with 5 subjects diagnosed with dry OAB and 31 patients diagnosed with wet OAB. Mean age of patients is 54, ranging from 18 to 77 years. Out of the total 36 enrolled patients, 34 subjects have reached either 3 or 6 months follow up. Study completion (last 6 months follow up) is expected by April 2016. The partial analysis of the first 12 subjects showed that 58% of subjects had ≥50% improvement at last follow up (either 3 or 6 months) in average leaks/day or voids/day or moderate-severe urgency episodes or a return to normal voiding frequency (<8 voids/day). Additionally, 33% of subjects experienced 30-50% improvement. Number or voids/day decreased significantly at last follow up in comparison to baseline (8.63 vs. 11.6, $p<0.05$) and moderate-severe urgency episodes also decreased significantly at last follow up in comparison to baseline (4.3 vs. 7.64; $p<0.05$). Subjects with wet OAB at baseline (9 out of 12), demonstrated a significant decrease in number of leaks/day at last follow up compare to baseline (4.15 vs. 6.56, $p<0.05$). Subjects showed statistically significant improvement from baseline to last follow up in all domains of OAB-q. There was a single serious adverse event (1/36; 2.8%). The implant was removed with no complications during or following the explantation procedure and the event was resolved with no further sequelae. Final results will be reported upon study completion at the ICS 2016.

Interpretation of results

The preliminary results of 12 out of 36 implanted subjects in the study suggest that the novel wireless miniature tibial nerve stimulator is feasible and safe and by a simple procedure offers an objective and subjective improvement for patients suffering from OAB.

Concluding message

This first in man, human feasibility trial conducted with a newly developed implantable tibial nerve stimulator will provide important information on the potential of this novel treatment technique.

References

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Disclosures

Funding: BlueWind Medical Ltd. **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov Identifier: NCT02299544 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Radboud universitair medisch centrum Concernstaf Kwaliteit en Veiligheid Commissie Mensgebonden Onderzoek Regio Arnhem-Nijmegen **Helsinki:** Yes **Informed Consent:** Yes