

## BLUEWIND MEDICAL RENOVA™ SYSTEM LONG-TERM SAFETY AND PERFORMANCE IN TREATMENT OF PATIENTS DIAGNOSED WITH OVERACTIVE BLADDER (OAB)

### Hypothesis / aims of study

To determine the safety and performance of the BlueWind Medical RENOVA System for the treatment of OAB for extended periods.

### Study design, materials and methods

Overactive bladder (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 or tibial nerve, with limited and preliminary publications on implantable tibial nerve stimulators (1,2). A novel peripheral neurostimulator device (BlueWind Medical Ltd.) for the treatment of OAB was developed; the implantable device electrically stimulates the tibial nerve at the site just proximally of the medial malleolus. The assumed working mechanism is that it modulates the neuronal afferent signals to the bladder, urinary sphincter and the pelvic floor. The implant 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). Herewith, the long-term safety and performance of the newly developed implantable peripheral neurostimulator, intended for home care use, is being observed for the treatment of patients with OAB.

Thirty-six patients with overactive bladder (OAB) with or without urge incontinence were enrolled in the original pilot study and implanted in a minimally invasive procedure of about 30 min, with an implant that was secured close to the tibial neurovascular bundle approximately 5 cm proximally to the medial malleolus. All patients were followed for 6 months. Three months results in a subgroup of 15 patients were published so far (3). In the present prospective, multi-center extension study, those patients are followed semi-annually for a period of 36 months after the system activation.

The endpoints of the study include incidence of serious adverse events and assessment of the OAB symptoms 36 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

Overall, most of the study patients who participated in the original pilot study have agreed to participate in the extended follow up. Up to now, 8 patients have reached 18 months follow up. Five of them have shown more than 50% improvement as compared to baseline (62.5%) and the other 3 (37.5%) have shown between 30-50% improvement as compared to baseline.

By September 2017, most of the patients are expected to reach their 24-month follow-up visit. Interim results will be reported upon reaching the planned follow-up visits.

### Interpretation of results

When comparing the results of the original study, which ended at 6 months follow up of the patients and the 18 months follow up, 4 patients remained with an improvement of more than 50%, 2 patients OAB symptoms were improved and in 2 patients OAB symptoms were deteriorated.

### Concluding message

The BlueWind Medical RENOVA System for the treatment of OAB has sustainable results after 18 months of activation

### References

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3. van Breda HM, Martens FM, Tromp J, Heesakkers JP. A new implanted posterior tibial nerve stimulator for the treatment of overactive bladder syndrome, three-months results of a novel therapy in a single center. *J Urol.* 2017 Feb 9. Epub ahead of print

### Disclosures

**Funding:** The support of BlueWind Medical Ltd. for this project is gratefully acknowledged. **Clinical Trial:** Yes **Registration Number:** NL50776.091.1 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** CMO Nijmegen The Netherlands **Helsinki:** Yes **Informed Consent:** Yes