

**EudraCT number:** 2007-003138-41

**Title:** Ensayo clínico para evaluar la seguridad de la toxina botulínica inyectada en esfínter uretral externo vía transperineal (esfinterotomía química) en la retención urinaria crónica secundaria a una lesión medular.

**Sponsor:** Hospital Universitario Vall d'Hebron. Barcelona. Spain

**Ended:** 2010

**Sponsor Protocol Code:** ROMBOX-01

## SUMMARY OF RESULTS:

### Background & Aims

Main objective was to assess the efficacy and safety of the botulinum toxin for sphincter hypertonia in patients with a spinal cord injury (SCI).

### Methods

Non control clinical trial on men with neurogenic detrusor-sphincter dyssynergia (DSD) due to a SCI. 100 UI of Botox® were injected through transperineal way on external urethral sphincter under electromyography and transrectal ultrasound guidance. The following parameters were determined: post-void residual (PVR), maximum urethral pressure (MUP), miction volum (M) and miction percentage (MP). The incidence of erectile dysfunction was evaluated using the International Index of Erectile Function questionnaire (IIEF-5 items).

### Results

19 men with an average age of 40 years (ED 22-56) were included. The average time of monitoring was 546 days (20 months). As an average, an infiltration was done every 6 months, with an average of 2.7 infiltrations per patient (1-7). PVR dropped by 59.3ml,  $p=0.03$ ; miction raised to 52ml,  $p=0.018$ ; MP was improved by 17.2%,  $p=0.011$ . Changes on MUP were not significant. Erectile dysfunction was not worse than the initial one (IIEF-5: 11.4 to 13).

### **Conclusions**

The infiltration of the toxin into the sphincter through transperineal way seems to be a suitable and safe therapeutic option

### **Publication**

Romero-Cullerés, G.; Conejero-Sugrañes, J.; González-Viejo, M.A.; Bruno-Montoro, J.; López-Guillen, P.; Abenoza-Guardiola, M.

Eficacia y seguridad de la toxina botulínica administrada en el esfínter uretral externo vía transperineal guiada mediante ecografía transrectal y electromiografía en la retención urinaria crónica secundaria a una lesión medul·lar.

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### **Detailed results are also available at:**

<https://www.tesisenred.net/handle/10803/52647#page=1>

PhD Thesis of Georgia Romero-Cullerés, Universitat de Barcelona (2010).

Title: APLICACIÓ DE TOXINA BOTULÍNICA TIPUS A VIA TRANSPERINEAL EN LA HIPERTONIA ESFÍNTER URETRAL EXTERN EN LA RETENCIÓ URINÀRIA CRÒNICA SECUNDÀRIA A UNA LESIÓ MEDUL·LAR.