Efficacy of Dropsordry supplementation on Urinary Incontinence in perimenopause.

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ABSTRACT

Urinary incontinence (UI) is a significant health problem with considerable social and economic impact. An estimated 30% of women aged 30 to 60 years old have urinary incontinence (UI). The objectives of this study was to examine the effect of the supplementation of tablets containing Dropsordry in women with urge urinary incontinence (UUI). Dropsordry is a novel active containing phytoestrogens from SOLGEN, the high genistin soy bean extract and pyrogallol plus polyphenols from standarized pumpkin seed extract,. The study was a single-center, not randomiized open prospective, study. 82 women with urinary incontinence ≥45 years were enrolled in this study (45-62 y. old age . Mean 52 y old). Items related to UI symptoms, were previously collected (T0) and these ítems were reviewed at the final of the study – 8 weeks. (T2). The presence of UI was previously diagnosed using the International Continence Society standards (ICS). Relationships between presence of UI and potential related factors as diabetes were also explored. Daily urinary test control was performed during the 8 weeks of treatment. Daily dosage was 1 g/ day (500 mg twice per day) from 0 to 4 week (T1), following a 500 mg/day daily intake from 4 to 8 week (T2). After eight weeks of treatment, the urgency grade score was reduced a 24,7%. The total urge episodes was reduced a 46%. Surprisingly there was no a significant change in daytime urinations (< 5%), however nocturia was reduced a 69,35%. Strenght Urinary Incontinence (SUI) was also tested showing a remarkably 52,17% reduction. Moreover the use of daily pantyliners was reduced a 66,25%. In addition, it was performed a panel test survey with quests when subjects of the study were enrolled (T0) and the same quests was performed after 8 weeks of supplementation (T2). 100% of the enrolled women fullfilled the ICIQ-SF quest (Spanish versión) and they were also questioned about the effects they noticed in response to taking the supplement and the change in quality of life. Interestingly no side effects were reported. There was a 96,2% of subjective satisfaction and a 85,8% objective score in the improvement of quality of life.

CLINICAL STUDY DESCRIPTION

- A 8 weeks single-center, prospective, not randomized open label study was conducted in Spanish women.
- **82 women with UI were enrolled (45-62 y. old)**. Items related to UI symptoms, were previously collected (T0).
- The presence of UI was previously diagnosed using the ICS standards.
- Relationships between UI and potential related factors were previously explored.
- Two tablets containing **500 mg of Dropsordry™ were supplemented during the first 4 weeks (T1), following a solely tablet supplementation containing 500 mg of Dropsordy™ from 5th to 8th week (T2).**

Dropsordry™ composition: SOLGEN soy isoflavones, and a *Cucurbita pepo*

- An analysis of the efficacy of Dropsordry™ on the different common types of UI (urgency and stress) it was carried out in this study.
- Daily records of micturition frequency at day and night were tested. Urgency micturitions were classified and tested during the supplementation. In addition different symptoms of stress urinary incontinence were analyzed before and after the treatment.
- 100% of the enrolled women fulfilled the ICIQ-SF quest.

DISCUSSION

Droposordry™ is a proprietary compounding containg high levels of genistein/ genistin from SOLGEN soy isoflavones and enterodiol/pyrogallol from pumpkin seed extract. The potential benefits of this actives on Urinary incontinence was tested in Spanish women.

There are remarkable benefits of Drosposordry™ supplementation during perimenopause regarding the different types of Urinary incontinence.

URGE URINARY INCONTINCENCE

- **REDUCTION IN URGENCY INCONTINENCE 46% (FIG.1)**
- **THE URGENCY GRADE SCORE WAS REDUCED 25% (FIG.3)**
- **DECREASE IN EPISODES OF URINE LACKAGE BEFORE REACHING TO THE TOILET 72,8% (FIG.5)**

STRESS URINARY INCONTINCENCE

- **DECREASE IN THE FREQUENCY OF STRESS EPISODES 66,26% (FIG.2)**
- **REDUCTION IN THE NUMBER OF EPISODES OF URINE LAKAGE BY EFFORT 25% (FIG.4).**
- **THE URINE LEACKAGE WHEN COUGHING OR SNEEZING INCIDENCENS WAS REDUCED 52,17% (FIG.6)**

ICIQ-SF TEST

- **74/ 82 of the enrolled women (90%) were very satisfied or satisfied with the supplementation**
- **78/82 of the enrolled women certify that they were very satisfied or certify with the Droposordry™ supplementation**
- **Solely 6 women reported side effects, but not significant enough and they could complete the supplementation during all along the clinical study.**

The supplementation of Droposordry™ during perimenopause seems to relieve some of the symptoms of urinary incontinence. It has been previously reported that estrogen deficit seems to be related with the increasing in muscarinic receptors, which mediate reflexive bladder contractions. Nervous dysregulation is the cause of OAB and Urge urinary incontinence as a consequence.

Enterodiol from *Cucurbita pepo* in Dropsordry™ when interacts with receptors on levator ani triggers an anabolic effect on pelvic muscles. The high Genistin concentration in Dropsordry™ compounding regrets the degenerative changes associated at OAB symptoms (**FIG. 1, 3, 5**).

RESULTS

FIG. 1.

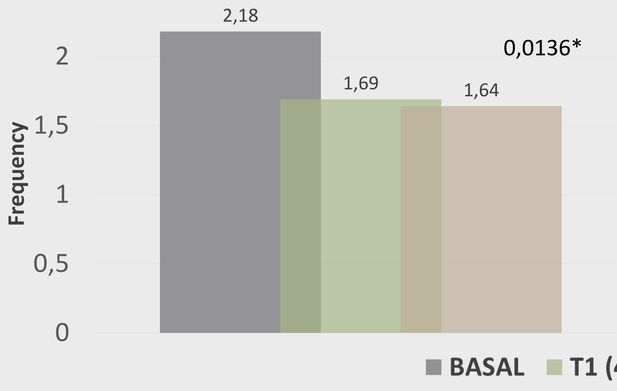


FIG. 2.

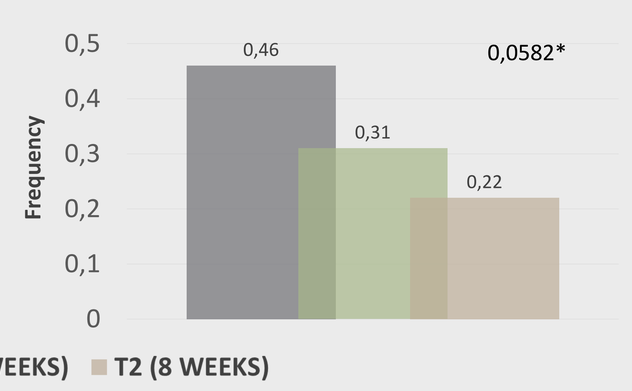


FIG. 3.

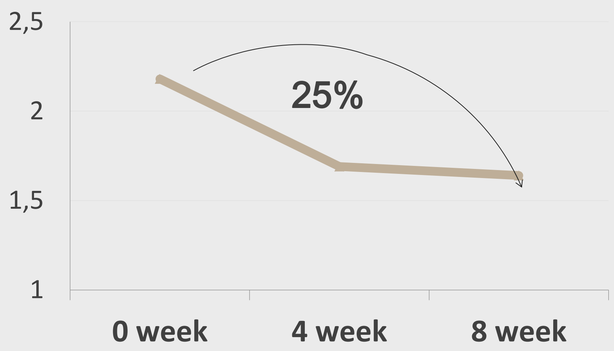
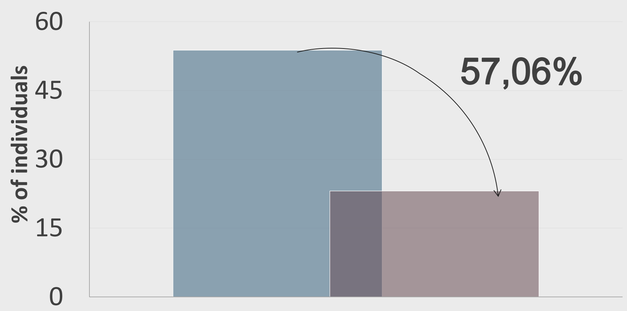


FIG. 4.



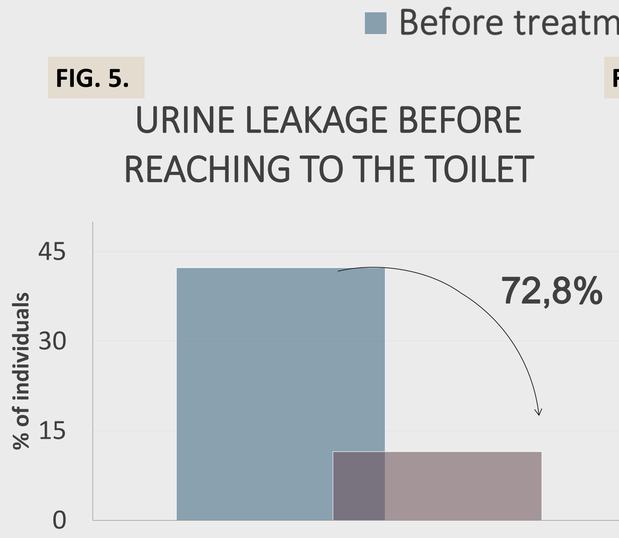
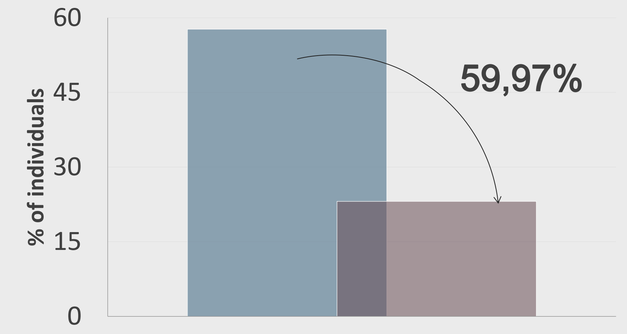


FIG. 5.

FIG. 6.



Clinical study and ICIQ-SF quest revealed that a sustained and long term supplementation of Droposordry™ seems a good strategy for the treatment of mild urinary incontinence in terms of safety and effectiveness.