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P2. CONTRACEPTIVE VAGINAL RINGS HAVE ADVANTAGES IN EFFICACY, SAFETY AND ACCEPTABILITY.

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Objective: To evaluate the safety, tolerability and acceptability as part of the clinical development of the recently developed contraceptive vaginal ring compared to the reference product. Comparative bioavailability is presented in separated communication.
Subjects: 40 healthy female.
Intervention: According to a randomized, single dose, 2-period, 2 sequence design, all subjects worn each vaginal ring during periods of 28 days, separated by a washout of 28 days: the vaginal ring recently developed by LeonFarma,Spain (Etonogestrel/Ethinylestradiol 120/15Âµg/day) and NuvaringÂ®, MSD,Spain (Etonogestrel/Ethinylestradiol 120/15Âµg/day).
Outcomes: Safety was assessed by means of adverse events (AE) recording and clinical laboratory. Local tolerability was evaluated by vaginal examination prior and at the end of each period. Acceptability was investigated by a 5-point scale questionnaire after each ring removal. AE were classified and described according to MedDRA dictionary. The questionnaires of local tolerability and acceptability were compared using the Cochran-Armitage Test for Trend.
Results: No serious AE and no deaths were reported. One subject was withdrawn for safety reasons (mild anaemia judged not related). Mild to severe AEs were reported by 30 of the 40 subjects with similar incidence between treatments, 77 with LeonFarma ring and 89 with NuvaringÂ®. The most commonly AEs experienced were vessel puncture site bruise (LeonFarma ring: 14% / Nuvaring: 15%), nausea (11%/15%), headache (14%/10%), abdominal pain (6%/15%), menstruation delayed (11%/8%), dizziness (9%/10%), and fatigue (9%/10%). The clinical laboratory values were not considered clinically significant except one mild anaemia and one urinary tract infection. Vaginal tolerability showed that 1 subject from each group showed mild vaginal mucosa irritation (p=1.000). Regarding acceptability, no differences were found in comfortability of use (p=0.336); interference with daily activities (p=0.904); discomfort during intercourse (p=1.000); felt by partner (p=0.275). Facility of reinsertion could not be calculated.
Conclusion: both products were well tolerated, with similar safety and local tolerability and both were well accepted.

[1] Chemo Group, [2] Chemo Group, [3] Chemo Group, [4] Leon Farma, Chemo Group