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Adhesion prevention in endometriosis surgery using 4DryField® PH – a prospective, randomized, controlled clinical trial

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Introduction: Adhesion formation after endometriosis surgery is a severe problem affecting up to 90% of patients. Its possible complications include chronic pain, ileus and secondary infertility. Therefore, effective adhesion prevention is desirable, for which the adhesion barrier 4DryField® PH is evaluated in the present study. It is a starch-based powder to be mixed with saline solution to form a gel layer acting as a physical barrier between wound areas and enabling their separated healing.

Methods: So far, 26 patients have completed both surgeries in this ongoing clinical trial with treatment of deep infiltrating endometriosis performed in a two-staged approach. The patients have been randomized into two groups, one with application of 4DryField® PH and the other receiving flushing with saline solution for adhesion prevention. Adhesion formation was directly scored during second look interventions considering incidence, extent and severity. Adhesion prevention treatment in the second surgery was performed corresponding to the treatment in the first intervention to evaluate the long-term outcome in the later course. Secondary endpoints include development of post-operative pain at different time points, as well as frequencies of wound healing disturbances, infections, abscesses, reoperations for adhesiolysis and pregnancies.

Results: Both groups were comparable with respect to relevant parameters. As only 26 patients have completed both surgeries so far, only interim results are currently available. Nevertheless, the results show a distinct reduction of adhesion formation when 4DryField® PH was used. The mean total adhesion score was reduced by more than 75%, likely prefiguring a significant difference upon completion of the study. No meaningful intermediate data is available for the secondary endpoints as none of the patients has completed follow-up so far.

Conclusion: Interim results of this prospective, randomized, controlled clinical trial on the use of 4DryField® PH in endometriosis surgery for adhesion prevention indicate that adhesion scores may be reduced by more than 75% compared to a control group receiving flushing with saline solution.

Keywords: Clinical study, Laparoscopy, Deep infiltrating endometriosis, Second Look, Adhesion prophylaxis, 4DryField® PH, Modified polysaccharide, Barrier gel

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