Reviewer's report

Title: BIOLAP: Biological versus synthetic mesh in laparo-endoscopic inguinal hernia repair: Study protocol for a randomized multicenter, self-controlled clinical trial

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Reviewer: F Köckerling

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BIOLAP is an excellent study protocol of a prospective, blinded, self-controlled randomized trial comparing laparo-endoscopic repair of bilateral inguinal hernias on one side with a synthetic and the other side with a biologic mesh. The randomization, on which side the biologic mesh will be used, takes place up to 72 before surgery. It is hypothesized that the use of a biological mesh reduces postoperative pain without increasing the recurrence rate. The primary endpoints will be the incidence of postoperative and chronic pain, separately evaluated for each repaired side per patient, and the incidence of recurrent hernia within the first 2 years after the operation, finally diagnosed by ultrasound, CT-scan or MRI. Study participants will not be informed about the location of the different mesh types. As this study design makes each patient his or her own control, it allows for an ideal comparison of biological and synthetic meshes without confounding factors.

The calculated case number assuming a 10% rate of loss to follow-up needs a total of 496 randomized patients. Overall 10 Monitoring visits will be performed at each Trial site.

The study is approved by the responsible Ethic Committe. Written informed consent will be obtained from all participants prior to their participation. The study is registered at the German Clinical Trials Register. The RCT is an investigator initiated trial financed by the German Research Foundation with 1.087.663 Euros.

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