Trial Title

Randomized double-blind controlled multicenter trial comparing suture and mesh repair in small umbilical hernias in adults

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Trial Code

SUMMER trial

Trial Registration Number

ClinicalTrials.gov Identifier: NCT04231071

SUMMER Trial – Statistical Analysis Plan (SAP)

Randomization

Patient will be allocated through the ECRF-system using pre-generated randomization lists. The randomization will be conducted using a block randomization with 1:1 relationship to the two procedures stratified by centre and defect size (≤ 10 mm and >10 mm). Total concealment of the allocation will be achieved with 4 or 6 block random sequence generation. Blinding of participants and follow-up surgeons with blinding of outcome assessment.

Analysis

- **ITT – Intention to treat**

All analysis will be made using an intention to treat procedure. Corresponding per-protocol analysis will be made and results from this analysis will be attached as a supplement in the final publication. All statistical tests will be two-sided using a significance level of $\alpha = 0.05$.

- **Primary endpoint**

To evaluate whether an onlay mesh in the repair of primary small umbilical hernias ≤ 2 cm reduces the risk of recurrence compared to suture repair 1 year and 3 year after surgery.

The primary endpoint is the recurrence rate during a follow-up period of 30 days, 12 and 36 months and will be analyzed using a logistic regression model with dummy variables specifying each time of follow-up. The analysis will be adjusted for centre, defect size and BMI. Reciprocal Kaplan-Meier curves will be generated to illustrate time to recurrence.

In order to detect a difference in recurrence rate of 9 pp after 36 months, assuming a recurrence rate of 3% with the use of mesh and 12% with a suture repair a sample size of 288 (144 in each

group) will be required to achieve a power of 80% at a significance level of $\alpha = 0.05$, allowing for a dropout frequency of 10%.

- **Secondary endpoints**

Secondary outcomes that will be analyzed by comparing the treatment groups are postoperative complications 30 days after surgery (Clavien Dindo scale), postoperative pain 1 year after surgery (assessed with Ventral Hernia Pain Questionnaire), postoperative complications 1 year after surgery. Postoperative complications and postoperative pain will be analyzed using ordinal logistic regression. Presence of postoperative complications will be analyzed using binary logistic regression.