

Antimicrobial prophylaxis for 1 day versus 3 days in liver cancer surgery: a randomized controlled non-inferiority trial

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Abstrak

ABSTRACT

Purposes This study compared the effectiveness of 1 day vs 3 days antibiotic regimen to prevent surgical site infection (SSI) in open liver resection.

Method

We performed a randomized controlled non inferiority trial in 480 patients at 39 hospitals across Japan (registered as UMIN000002852). Patients with hepatocellular carcinoma scheduled to undergo resection were randomly assigned to receive either a 1 day regimen for antimicrobial prophylaxis, or a 3 day regimen. The primary endpoint was the incidence of SSI.

Results

Among 480 randomized patients, 232 assigned to the 1 day regimen and 235 to the 3 day regimen were included in the full analysis set. Baseline characteristics of the two groups were well balanced. SSI was diagnosed in 22 patients (9,5%) in the 1 day group vs 23 patients (9,8%) in the 3 day group (difference, -0,30; 90% CI -4,80 to 4,19% (95% CI -5,66% to 5,05%); one sided P=0,001 for non inferiority), meeting the non inferiority hypothesis. In both groups, remote site infection (16 (6,9%) vs 22 (9,4%), P 0,001 for non inferiority) and drain-related infection (5 (2,2%) vs 4 (1,7%), P 0.001 for non inferiority) were comparable.

Conclusion

To prevent SSI in liver cancer surgery, a 1 day regimen of flomoxef sodium is recommended for antimicrobial prophylaxis because of confirming the non-inferiority to longer usage.