Multicenter randomized phase II study comparing alternate-day oral therapy using S-1 with the standard regimen as a first-line treatment for locally advanced and metastatic pancreatic cancer: PAN-01 study.

Background
- S-1 is an active agent for the treatment of pancreatic cancer (PC).
- GEST study has previously shown the noninferiority of S-1 to gemcitabine in advanced PC.
- Alternative-day administration may be a treatment option.

Study design
- Non-inferiority
  - Study aim: Comparison of S-1 compared to the standard regimen for advanced PC.
  - Study design: Multicenter randomized phase II study comparing alternate-day oral therapy using S-1 with the standard regimen as a first-line treatment for patients with locally advanced and metastatic pancreatic cancer: PAN-01 study.

Key eligibility criteria
- Pathologically confirmed unresectable PC
- Age between 20 and 79 years
- PS 0 or 1 (ECOG)
- No prior chemotherapy/radiotherapy

Statistics
- 180 patients required
  - 95% credible interval was also calculated for HR
  - Non-inferiority threshold HR: 1.33
  - Alpha error: 0.05, Power: 80%

Survival analysis
- Median OS: 10.4 M vs 10.4 M (HR, 1.19; 95% CI, 0.86-1.64).
- Median PFS: 3.0 M vs 4.2 M (HR, 1.65; 95% CI, 1.20-2.29).

Adverse events
- PAN-01 did not show the noninferiority of alternate-day administration to standard regimen in overall survival.
- PAN-01 demonstrated that alternate-day administration was significantly worse than standard regimen in tumor progression.

Conclusion
- This study failed to demonstrate the noninferiority of alternate-day administration of S-1 to standard regimen as a first-line chemotherapy in unresectable pancreatic cancer.

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