Fixed-dose adjuvant subcutaneous (s.c.) trastuzumab (T) has been reported to have a lower incidence of cardiac toxicity compared to intravenous (i.v.) administration, and fixed-dose s.c.-T has already been approved for the treatment of early breast cancer patients. However, non-clinical data from cynomolgus monkeys showed that T had a lower clearance in s.c.-administered T compared to i.v.-administered T. We conducted a phase I study to evaluate the pharmacokinetics (PK) of s.c.-T vs. i.v.-T in healthy subjects and early breast cancer patients. PK parameters median (range) were similar for s.c.-T and i.v.-T in healthy subjects. AUClast and Cmax were similar for s.c.-T and i.v.-T in breast cancer patients. No additional treatment-related cardiac events were observed. Our study confirmed the safety of subcutaneous T administration but did not prove PK equivalence between the two routes.

**Conclusions:** The PK of s.c.-T vs. i.v.-T is consistent in healthy subjects and breast cancer patients. Further studies are required to establish PK equivalence between the two routes.

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