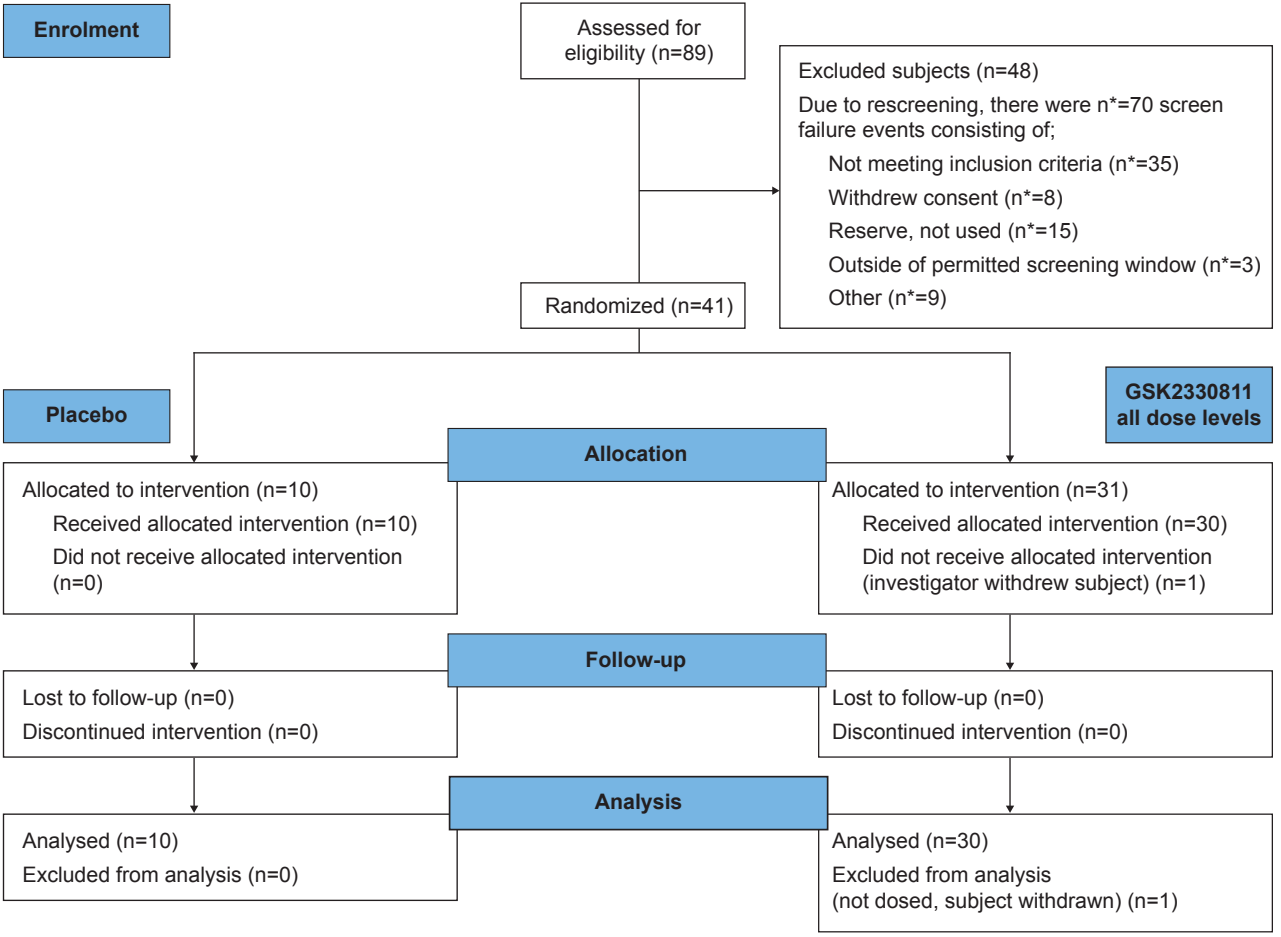

n*=number of screen failure events (subjects failing screening could be rescreened, therefore n* [screen failure events] exceeds n [subjects]. Subjects were only randomized once).