21. Others

Reference

Kita T, Sumino M. The effect of dosage frequency of ethical Kampo extract formulations on drug compliance – a comparison of twice a day and three times a day prescriptions. *Igaku to Yakugaku* (*Japanese Journal of Medicine and Pharmaceutical Science*) 2011; 66: 117–22 (in Japanese). Ichushi Web ID: 2011300492 MOL, MOL-Lib

1. Objectives

To assess whether differences in ethical Kampo extract formulation dosage and dosing frequency have an effect on compliance and patient satisfaction.

2. Design

Crossover randomized controlled trial (RCT – cross over).

3. Setting

Not specified (the authors are from the Center for Environment, Health and Field Sciences, Chiba University.), Japan.

4. Participants

One hundred and five outpatients who had been taking ethical Kampo extract formulation for chronic disease or symptoms for more than one month, whose condition had stabilized, and who gave their consent.

5. Intervention

Kracie KB - stick packages (twice a day) and Kracie EK - stick packages (three times a day) containing the same ethical Kampo extract formulation as currently being taken. Administered for one week each.

Arm 1: three times a day for the first week, then twice a day for the second week (n=54).

Arm 2: twice a day for the first week, then three times a day for the second week (n=55).

6. Main outcome measures

Questionnaire on dosing circumstances (timing, whether dosing was missed, and how often dosing was missed), patients' satisfaction with frequency and dosage (5-step scale: satisfied, slightly satisfied, no change, slightly dissatisfied, dissatisfied), and lifestyle (which suits lifestyle better, twice a day or three times a day) during each period.

7. Main results

In arm 1, dosing was missed in 36 of 54 participants during the first week (three times a day) and 15 of 54 participants in the second week (twice a day), which meant a significant difference ($P<0.0001$). Similarly, there was a significant difference in missed dosing in arm 2 ($P<0.001$). The mean amount and proportion of left-over medication was 2.0 ± 2.2 packages and $9.4\pm10.4\%$, respectively, during the three-times-a-day period and 0.4 ± 0.8 and $2.8\pm6.0\%$ respectively during the twice-a-day period. There was a significant difference in the proportion of left-over medication between the periods ($P<0.0001$). Participants missed their medication most often around midday (63 participants, 87.5%) during the three-times-a-day period. Thirty-nine participants (72.2%) were satisfied or slightly satisfied in arm 1, where dosage frequency decreased in the second week, while 36 participants (65.5%) were satisfied or slightly satisfied in arm 2, where dosage frequency increased in the second week. Ninety-four participants (86.2%) chose the twice-a-day medication for consistency with lifestyle, while 6 participants chose the three-times-a-day medication (5.5%) and 9 (8.3%) were indifferent.

8. Conclusions

Reducing the frequency of Kampo extract preparation dosing from three to two times a day decreases missed dosing, and therefore is an effective means of improving compliance.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This RCT employed different dosing frequencies in the intervention and measured outcomes in terms of dosing compliance and satisfaction. This trial is, therefore, very instructive in that it demonstrates that such an approach can be used in an RCT. It also has great clinical significance in the sense that doctors' prescribing behavior can change patients' dosing compliance. Researchers should be encouraged to develop further research along these lines, perhaps by including symptoms among the outcomes.

12. Abstractor and date

Tsuruoka K, 31 December 2012.