

21. Others

Reference

Takahashi H, Nakao R, Hirasaka K, et al. Effects of single administration of Rokumi-gan (TJ-87) on serum amino acid concentration of 6 healthy Japanese male volunteers. *Journal of Medical Investigation* 2007; 54: 91-8. Ichushi Web ID: 2007295608 [J-STAGE](#)

1. Objectives

To evaluate effects of rokumigan (六味丸) on serum amino acid concentrations.

2. Design

Randomized crossover controlled trial (RCT-cross over).

3. Setting

Department of Internal Medicine, the Komatsushima Hospital, Japan.

4. Participants

Six healthy men (mean age 35.5 years), n=6.

5. Intervention

Arm 1: lactose 5 g administered once at 9:00, n=6.

Arm 2: Asahi amino GET 5 tablets (contains a similar amount of amino acids as 10 g of Tsumura Rokumigan (六味丸) Extract Granules) administered once at 9:00, n=6.

Arm 3: Tsumura Rokumigan (六味丸) Extract Granules (TJ-87) 10 g administered once at 9:00, n=6.

There was a washout period of 3 months between treatments.

6. Main outcome measures

Serum amino acid concentrations before and at 1, 2, 4, and 6 h after the intervention.

7. Main results

In arm 1, concentrations of Ala, Gly, and Ile were significantly decreased from pretreatment levels at 6 h, and Arg, Glu, His, Leu, Lys, Phe, Ser, and Val levels were unchanged. In arm 2, concentrations of Ala, Glu, Gly, Ile, Leu, and Ser were significantly decreased at 6 h, but Arg, His, Lys, Phe, and Val levels remained unchanged. In arm 3, the levels of Ala at 2 h and Gly and Ser at 1 h were significantly increased, but Arg, Glu, His, Ile, Leu, Lys, Phe, and Val levels remained unchanged. In all three arms, serum levels of Asn, Cys, Gln, Met, Pro, Thr, Trp, and Tyr were not determined, and Asp were undetectable.

8. Conclusions

Serum amino acid concentrations are higher after administration of rokumigan than after administration of a supplement containing a similar amount of amino acids.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not documented.

11. Abstractor's comments

This interesting well-designed cross-over clinical trial investigates the entry of amino acids from rokumigan into the blood. Changes in the concentration of amino acids after rokumigan administration were compared with those after administration of lactose or an amino acid mixture containing almost the same amount of amino acids. Amino acid levels (e.g., the pretreatment Ala level) were widely dispersed in all three arms, suggesting possible measurement errors in serum level for some amino acids. To adjust for dispersion in the data, relative changes in amino acid concentrations were calculated and are shown in Fig. 1. However, symbols a, b, and c are not defined. Also, the amino acid mixture administered in arm 2 contains several ingredients besides amino acids such as beer yeast, and their influence on absorption should be considered. Importantly, this study found that administration of rokumigan increased amino acid levels in blood and suppressed the gradual decrease observed in other arms. This observation may have important pharmacologic implications. Further studies on several Kampo medicines are anticipated.

12. Abstractor and date

Goto H, 27 November 2008, 1 June 2010, 31 December 2013.