EFFECT OF MODIFIED TMF 15 AND MODIFIED TMF 16 ON PERIMENOPAUSAL PATIENTS

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ABSTRACT

The present study deals with "Effect of Modified TMF 15 and Modified TMF 16 on Perimenopausal Patients" which is a major health problem in women with long term consequence. The 44 patients suffering from perimenopausal symptoms were selected from Convent school, AungMyayTharZan Township in Mandalay by Random Sampling Method and conducted by Randomized Clinical Trial Design. The effectiveness of Modified TMF 15 and Modified TMF 16 on perimenopausal symptoms were evaluated by using assessment criteria on day 0, day 7, day 14, day 21 and day 28. The oral administration of Modified TMF 15 and Modified TMF 16 was conducted in two groups of patients. After giving the drug for four weeks, the outcomes of the two groups were compared. Statistical analysis on Two-way ANOVA test and General Linear Model Method was done by using SPSS statistics (version 21). Observation the effect of Modified TMF 15 and Modified TMF 16 was made to compare before and after treatment. The effect of Modified TMF 15 on hot flushes/night sweating relieved 64.39% ($p<0.000$), insomnia 78.45% ($p<0.000$), palpitation 74.42% ($p<0.000$), muscle and joints pain 40.31% ($p<0.000$), irritability 48.88% ($p<0.000$), anxiety 36.99% ($p<0.003$), feeling tiredness 67.64% ($p<0.000$), dryness/itching in vagina 18.49% ($p<0.069$) and overall effect of Modified TMF 15 was 60.36% after treatment. The effect of Modified TMF 16 on hot flushes/night sweating relieved 65.35% ($p<0.000$), insomnia 62.89% ($p<0.000$), palpitation 63.67% ($p<0.000$), muscle and joints pain 59% ($p<0.000$), irritability 35.11% ($p<0.029$), anxiety 21.38% ($p<0.050$), feeling tiredness 62.62% ($p<0.000$), dryness/itching in vagina 60.78% ($p<0.000$) and overall effect of Modified TMF 16 was 57.59% after treatment. Modified TMF 15 was more potent on insomnia, palpitation, irritability, anxiety, feeling tiredness than Modified TMF 16 but patients with hot flushes/night sweating, muscle and joints pain and dryness/itching in vagina were more potent with Modified TMF 16 than Modified TMF 15. Concerning the effect of Modified TMF 15 and Modified TMF 16, the obtained results can be proved clinically and statistically effective for the management of perimenopausal symptoms by Modified TMF 15 and Modified TMF 16. The result of this study showed that the benefit of Modified TMF 15 was slightly significant than Modified TMF 16. Based on the findings, it is suggested that can be provided in the management of perimenopausal symptoms.

Keywords: Modified TMF 15 and Modified TMF 16, Perimenopause

ELEMENTAL ANALYSIS AND SAFETY OF *YASADA BHASMA* (ZINC ASH)

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ABSTRACT

Zinc ash is used in the treatment of urinary disorders, eye disorders, asthma, migraine, menorrhagia, dysmenorrhea, leucorrhoea, cough, fever, tremor, and as *Rasayana* drug in *Vijjadhara naya*. The present study was undertaken to determine elemental composition and safety of *Yasada Bhasma* (Zinc Ash) during 2017 - 2018.Zinc ash was prepared from purified zinc and powder of *Achyranthes aspera* L. by using special type of oven (*Mal-Kinn-Pho*) for 24 days.Elemental composition was analyzed by WDXRF at Department of Geology, University of Research Center, Mandalay.In elemental analysis, Al, Si, P, K, Ca, Cr, Fe, Cu, Zn, As, In, Sn and Pb as element and Al_2O_3, SiO_2, P_2O_5, K_2O, CaO, Cr_2O_3, Fe_2O_3, CuO, ZnO, As_2O_3, In_2O_3, SnO_2 and PbO as elemental oxide were detected.Zinc oxide (ZnO) was observed as main component in this drug. Acute and sub-acute toxicity studies were performed as per OECD guidelines 425 and 407 respectively at Department of Medical Research (Pyin Oo Lwin branch). In acute toxicity study, there was no observed death or toxic signs and symptoms, and no abnormalities on grossly features. It was determined that the LD_{50} of zinc ash was greater than 5000 mg/kg in male albino rats.In the repeated dose study, there was no observed death or toxic signs and symptoms. There was significant body weight gain in all groups. Grossly, there was no observed any morphological difference compared with the control group. There was observed normal histological appearance except mild vascular congestion compared with the control group. These mild histopathological changes were observed in kidney and liver of medium and high dose groups. The histopathological section of other organs revealed no failure on comparison with the control group. Therefore, it was concluded that *Yasada Bhasma* (zinc ash) was found to be free of any toxic effect under the condition of this study.

Keywords: Zinc Ash (*Yasada Bhasma*), Elemental Analysis, Safety

COMPARATIVE STUDY ON DIURETIC EFFECT BETWEEN TMF-21 AND COMBINED TMF-21 AND TMF-13

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ABSTRACT

Some traditional medicine formulations (TMFs) such as diuretics has been used in the treatment of hypertension, urinary disorders and oedema. TMF-21 (See-Hsay-Phyu) and TMF-13 (Wait-tan-bi-ta-say-phyu) are commonly used as the diuretic drugs in Traditional Medicine Hospitals. Both TMFs were experimentally and clinically found that they had diuretic effects. The combined TMF-21 and TMF-13 has been used as diuretic agent but no scientific report was available for its diuretic activity. Therefore, the diuretic activity of combined TMF-21 and TMF-13 was evaluated by comparing with TMF-21 on healthy volunteers. The study was randomized clinical trial conducted at University of Traditional Medicine and (100) Bedded Traditional Medicine Teaching Hospital, Mandalay. Study period was one year. In this study, the diuretic activity of TMF-21 and the combined TMF-21 and TMF-13 were evaluated in 64 healthy volunteers by using Randomized Clinical Trial design. The volunteers were chosen according to the selection criteria and then the informed consent was obtained. Four tablets of TMF-21 (500mg each) and four tablets of the combined TMF-21 and TMF-13 (500mg each) were given to each volunteer with water. The urine output within 8 hours (from 8:00am to 4:00pm) was collected and urine volume was measured with urine slender measuring cup. The diuretic effect between TMF-21 and combined TMF-21 and TMF-13 was determined by comparing mean urine volume of the volunteers by using SPSS version (21). In all healthy volunteers, the mean urine volume (Mean ± SD) before administration of TMF-21 was 963.98±450.27 ml/8hrs. After administration, it increased to 1197.34±530.17 ml/8hrs and p value was 0.000. The mean urine volume before administration of combined TMF-21 and TMF-13 was 963.98±450.27 ml/8hrs. After administration, it increased to 1380.63±526.22 ml/8hrs and p value was 0.000. Therefore, urine volume were significantly increased before and after administration of TMF-21 and the combined TMF-21 and TMF-13. The mean urine volume after administration of combined TMF-21 and TMF-13 was increased by 183.29 ml/8hrs (mean difference) compared with TMF-21 and p value was 0.000. Therefore, urine volume was significantly improved by the administration of combined TMF-21 and TMF-13 in this study. No adverse reaction was observed. Therefore, the study supported the fact that the combined TMF-21 and TMF-13 can be used as the diuretic agent safely.

Keywords: Diuretic effect, Combined Traditional Medicine Formulation (TMF) 13 and 21

Elemental Analysis of GANDHAKA BHASMA (Kant-Pyar) and Its Acute and Sub-acute Toxicity Study

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ABSTRACT

In Myanmar Traditional Medicine, Gandhaka Bhasma (Kant-Pyar) is mainly used in the treatment of chronic diseases such as stroke, obesity, arthritis, heart disease, cancer and type 2 diabetes. It is also used as Rasayana drug in Vijjadharanaya. Although the ancient books composed of poems and verse about heating methods for the preparation of Kant-Pyar, without describing them as evidence. Nowadays Alchemist have to find out the meaning in various ways. Heating methods and heating duration are different about the preparations. There was a saying that on the preparations of metallic medicine with higher temperature on heating the metals become more inert and will get the greater valuable effects thus as less toxic effects but there was no scientific study. Therefore, GandhakaBhasma (Kant-Pyar) was prepared by 1 month, 2 months and 4 months of heating durations and after that, the elemental analysis of each preparations and toxicity studies were carried out. Elemental compositions of raw sulphur, purified sulphur and Kant-Pyar (1 month, 2 months and 4 months) were analyzed by EDXRF at MGA Petrochemical Lab Mandalay. The percent of sulphur element containing, 1 month baking of KP was decreasing than purified sulphur, 2 months baking of KP was increasing than 1 month baking of KP and 4 months baking of KP was increasing than 2 months baking of KP. The percent of other element included in raw sulphur, purified sulphur, 1 month and 2 months baking of KP were the lowest containing in 4 months baking of KP. Acute and sub-acute toxicity studies of Kant-Pyar at 2 months and 4 months heating duration were performed by OECD guidelines 425 and 407 respectively. In acute oral toxicity study of these two preparations, was determined the LD50 greater than 5000 mg/kg in fasted male rats. On sub-acute toxicity study, 2 months heating duration of Kant-Pyar showed that kidney (tubular atrophy and casts, vessel wall thickening, glomerular atrophy and sclerosis) and liver (lymphocytic infiltration and dilated vein). iiOn 4 months heating duration of Kant-Pyar showed that normal histopathological features on all organs apart from liver with mild congestion.

Keywords: Elemental Analysis, Kant-Pyar, Acute and Sub-acute Toxicity

Comparative Study of Lipid Lowering Effect between Traditional Medicine Formulation (TMF)-23 and (TMF)-28

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ABSTRACT

This present study was aimed to find out the lipid lowering effect between Traditional Medicine Formulation (TMF)-23 and (TMF)-28 on healthy volunteers from Monastery and Convent in Mahar-Aungmyay Township, Mandalay. It was a randomized clinical trial carried out from August 2017 to June 2018. TMF-23 and TMF-28 used in this study were prepared in Myanmar Traditional Medicine Factory, Mandalay. All tests for evaluation of tablet dosage form were within acceptable range. In the present study, 40 cases with hyperlipidemia were studied for the lipid lowering effect. The duration of drug taken for each participant was 60 days. The lipid lowering effect was determined by measuring serum total cholesterol level, triglycerides level, low density lipoprotein level and high density lipoprotein level on day-0 (before administration) and 8^{th} week (after administration). Statistical analysis on paired *t*-test and one way ANOVA method was done by using SPSS statistics (version 21). In TMF-23 group, TC, TG and LDL level were significantly reduced after 8^{th} week (p = 0.000, p = 0.000 and p= 0.036 respectively).In TMF-28 group, TG level was significantly reduced (p = 0.000) after 8^{th} week and although TC level was reduced after 8^{th} week, it was not statistically significant (p = 0.076). In TMF-28 group, mean difference of LDL level was -10.69 (p = 0.247) and LDL level was increased after 8^{th} week. Moreover, although HDL level at day-0 was slightly increased by -5.68 (p= 0.104) after 8^{th} week in TMF-23 groups, HDL level at day-0 was slightly decreased by 5.96 (p = 0.078) after 8^{th} week in TMF-28 groups. But, the reduced HDL level of individual participants in TMF-28 group was within normal range. The comparison of lipid lowering effect between TMF-23 and TMF-28 were not remarkable according to the result findings. TMF-23 (*Say-Pale-Kalat*) and TMF-28 (*Thet-Yin-Kalat-Say*) used in this study have been widely used by various pathological conditions especially treatment in stroke and neurological diseases related to hyperlipidemia without adverse effect. Therefore, these two drugs can be applied in prevention of hyperlipidemia and its related diseases.

Keywords: Traditional Medicine Formulation (TMF)-23 and (TMF)-28, Lipid Lowering Effect

ANTI-HYPERGLYCAEMIC EFFECT OF MODIFIED TMF-17 ON TYPE 2 DIABETES MELLITUS PATIENTS

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ABSTRACT

In traditional medicine, TMF-17 has been experimentally used to treat hypertension and diabetes mellitus. Diabetes mellitus is termed as *Madhumeha* in *Ayurvedic*Medicine. It was *Sangahita* type of the disease in *Desana* Medicine and can be treated with hot, bitter and pungent taste of the drugs. This study was aimed to determine the anti-hyperglycaemic effect of modified TMF-17 on type 2 diabetes mellitus patients. Long term use of the drug need to prevent some complications in type 2 diabetes patients. Camphor and nagi camphor were removed from the original TMF-17 to prepare modified TMF-17. All patients between the age of 40-60 years, admitted to 100 bedded TMTH, Mandalay, were screened for type 2 diabetes mellitus and among -them, twenty-two were selected with the inclusion criteria. These patients who gave inform consent for participation were conducted hospital based clinical trial according to objectives of determining anti-hyperglycaemic effect of modified TMF-17 on type 2 diabetes mellitus patients. Before the intervention, screening of FBS, 2HPP, ECG, serum urea and creatinine were done. The modified formula was prepared tablet dosage form to promote patient compliance and all patients took seven tablets (300 mg/tablet) three times per day before the meal after getting diet control and regular physical exercise advice. Daily FBS and 2HPP blood sugar levels were measured from the capillary by using the glucometer with the observation of any adverse effect during the intervention. The mean FBS and mean 2HPP levels were compared at day -0, day-7, day-14 and day-21. The blood glucose levels were significantly reduced from 235.86 ± 55.5 to 201.04 ± 44.6, 173.36 ± 37.2 and 149.68 ± 21.9 mg/dL respectively (p<0.0001). As for 2HPP level, from 370.22 ± 66.5 significantly reduced to 310.31 ±66.4, 267.68 ± 68.6 and 226.68 ± 63.3 mg/dL (p<0.0001). There was no severhyperglycaemic or hypoglycaemic in patients during the study period. Therefor the present study reveals that there was anti-hyperglycaemic effect of modified TMF-17 on type 2 diabetes mellitus patients without complications.

Key Words: Modified TMF-17, Diabetes Mellitus, Anti-hyperglycaemic, Traditional Medicine.

SAFETY AND EFFICACY OF ANTI-HYPERTENSIVE DRUG (TMR-009829) ON PATIENTS WITH MODERATE HYPERTENSION

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ABSTRACT

This study was carried out to determine the antihypertensive effect of the antihypertensive drug (TMR-009829) from July, 2017 to June, 2018. The preliminary phytochemical constituents and physicochemical properties of this drug were determined. In acute toxicity study, the median lethal dose (LD50) of this drug was determined that was greater than 5000 mg/kg. The sub-acute toxicity study was conducted according to OECD guideline 407 for 28 days. There was assigned into 4 groups including control group and each group contains 6 rats. In this study, the three different dose levels of 500 mg/kg, 1000 mg/kg and 2000 mg/kg of test drug were given to the rats. There were no changes in clinical observations, morbidity or mortality, abnormalities in gross features both control group and test groups of antihypertensive drug (TMR-009829). According to histopathological study, the antihypertensive drug (TMR-009829) posses no acute toxic effect and sub-acute toxic effect on experimental albino rats. A clinical trial was carried out on 27 moderate hypertensive patients by using simple random sampling method. Participants of Phone Taw Toe quarter, Buddhist monks and nuns in Aung Myay Thar San Township, Mandalay were selected. Urea, creatinine and ECG were investigated before the drug administration. After washout period of 3 days, patients were treated orally with antihypertensive drug (TMR-009829) tablet 2 g (5 tablets) two times daily for 4 weeks. After 4 weeks of treatment with this drug, the results showed that significant reduction of mean systolic and diastolic blood pressure was from 166.70 ± 6.348 mmHg to 141 ± 13.344 mmHg and from 104.11 ± 4.246 mmHg to 89.26 ± 8.286 mmHg (baseline day 0 - day 28) respectively. It was observed that this trial drug decreased the mean systolic blood pressure and diastolic blood pressure from baseline level by 25.407 mmHg ($p<0.000$) and 14.852 mmHg ($p<0.000$) respectively. Therefore, it can be concluded that antihypertensive drug (TMR-009829) showed significant antihypertensive effect on moderate hypertensive patients.

Keywords: Traditional Medicine Antihypertensive Drug (TMR-009829), Moderate Hypertensive Patients.

SAFETY AND ANTIHYPERGLYCEMIC EFFECT OF *HSI-GJOU-KJA-HSEI* (NO.1, 2 AND 3) ON TYPE 2 DIABETES MELLITUS PATIENTS

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ABSTRACT

This hospital based clinical study was attempted to investigate the antihyperglycemic effect of HGKH (No. 1, 2 and 3) pills in 20 outpatients, both sexes, at 100 bedded TMTH, Mandalay, from 1July 2017 to 30June 2018. The three drugs are hot and HGKH (No.1) is predominant in sweet and blunt sweet, (No.2) in pungent and (No.3) in bitter taste. The physicochemical analysis was performed for these three drugs and the results were acceptable ranges. The phytochemical investigations indicated the presence of alkaloids, flavonoids, glycosides, phenolic compounds, polyphenols, carbohydrates and tannins in all three drugs. The evaluation of pill form was within the acceptable range. Acute and sub-acute toxicity tests of HGKH (No.3) were performed with albino rats by OECD guided line (2008). There was no lethality up to the dose of 5000 mg/ kg b wt and sub-acute toxicity test, no significant change in body weight of the rats showed that this drug was safe for the rats and had no deleterious effect although there was mild congestion in liver and kidney of the high dose treated rats (500 mg/kg). In clinical study, the fasting blood sugar level and 2HPP level were measured at day 0, day 7, day 14, day 21, and day 28. The drugs prescribed pattern was 1500 mg (3 pills) of HGKH (No.1) in the morning, 1000 mg (2 pills) of HGKH (No.2) at noon and 1000 mg (4 pills) of HGKH (No. 3) in the evening after meal. The FBS level (Mean ± SD) 12.380 ± 3.443 mmol/L at day 0 was reduced to 11.61 ± 3.30 mmol/L at day 7, 10.64 ± 3.60 mmol/L at day14, 9.65 ± 2.87 mmol/L at day 21 and significantly reduced to 8.77 ± 2.63 mmol/L at day 28. In assessing 2HPP blood sugar level, (Mean ± SD) at day 0 was 19.12 ± 5.18 mmol/L and after administration were 17.71 ± 4.80 mmol/L, 15.14 ± 4.64 mmol/L, 12.88 ± 4.35 mmol/L and 11.36 ± 3.69 mmol/L. There were significantly reduced ($p = 0.000$) in FBS level and 2HPP level after test. The significant antihyperglycemic effect of HGKH (No.1, 2 and 3) could be due to the presence of the above components which could act synergistically and/or independently to enhance the antidiabetic activity. No significant side effect was experienced throughout the study. Thus, the tastes overwhelming in HGKH (No.1, 2 and 3) were effective for diabetes mellitus grouped in sangahita diseases. Therefore, this study proved that the prescription of these three types of drugs systemically could reduce and maintain the blood glucose level in diabetes mellitus patients.

Keywords: *Hsi-gjou-kja-hsei* (No.1, 2 and 3), Antihyperglycemic effect