M2-TONE

M2-TONE Syrup in treatment of Unexplained Infertility <u>in females</u>

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- The present study was designed to evaluate the role of M2-TONE syrup in the treatment of unexplained infertility
- 50 patients of unexplained infertility with mean age: 27.88 ± 3.30 years in a range 20 35 years were selected
- The investigator examined role of M2-TONE on ovulatory status, conception & menstrual abnormalities
- Effect of M2-TONE on ovulatory status: Ovulation was seen in 5 out of 9 (55%) anovulatory patients. The mechanism of action of M2-TONE here is its proven estrogenic activity which could have added to the critical pre-ovulatory blood concentration of oestradiol to trigger the mid-cycle LH surge. Further M2-TONE by restoring the delicate balance between the hypothalamus-pituitary-ovarian axis could have stimulated ovulation
- Effect of M2-TONE on conception: Pregnancy was noted in 7 out of 21 (33.3%) ovulating patients on M2-TONE in contrast to one on placebo
- Effect of M2-T0NE on menstrual abnormalities: In the present study in 36.3% patients on M2-TONE the irregular cycles normalized, while 100% response was seen in patients of menorrhagia treated with M2-TONE. Similarly, a 100% response was also noted with M2-TONE in patients of hypomenorrhoea and around 75% patients treated with M2-TONE showed relief
- M2-TONE resulted in 33.3% conception rate with full safety in M2-TONE group, even though the duration of the trial was short (9 months). Additionally, in 36.3% women, M2-TONE cured menstrual irregularities

CONCLUSION

from spasmodic dysmenorrhoea

The mechanism by which M2-TONE acts is by its proven "estrogenic" effect on the female reproductive system. A very good rate of conception was achieved with M2-TONE syrup i.e. 33.3% as compared to 4% cases treated with placebo.

<u>Clinical evaluation of M2-Tone in Unexplained</u> <u>Infertility</u>

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- The present (uncontrolled) study assessed the efficacy of M2-T0NE syrup, a comprehensive non-hormonal herbomineral formulation, in the treatment of 165 women with unexplained infertility
- All female partners were treated with M2-TONE in the dose of two tablespoonfuls, three times daily for 3-6 months
- All female patients were followed-up on a two monthly basis throughout the treatment period and examined for signs of pregnancy and/or side effects of treatment
- The overall conception rate on M2-TONE was very good (33%)
- Menstrual irregularities associated with unexplained infertility were also improved by M2-TONE
- M2-TONE is a valuable alternative therapy in the gynaecological armamentarium for the treatment of unexplained infertility

Conclusion

M2-TONE- A comprehensive herbomineral formulation, achieved a very good rate of conception in unexplained infertility (33.3%). Thus M2-TONE offers a valuable alternative therapy for treatment of female infertility.

<u>Unexplained Infertility - Clinical Trial with M2-TONE</u> <u>syrup an Indigenous Product - A study of 104 cases</u>

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- The study was designed to evaluate the increase in the endometrial glycogen content in woman patients after use of M2-TONE
- 104 cases of infertility without evident organic causes were studied. Their age were between 25 to 40 years and comprised primary as well as secondary sterility. Endometrium of these patients was subjected to PAS staining for glycogen content. Depending upon the amount of glycogen particles: glycogen index was graded as Low, Moderate, Good
- Most of these (78 cases) were treated with M2-TONE syrup in a dose of 2 tspfult.d.s. for a period of 3 months. 22 cases were kept as control, conception occurred in 14 cases out of 28 (50%) with low glycogen index, 24 cases out of 34 (70%) with moderate index and 4 out of 20 (20%) with good glycogen index and 1 out of 22 (4.5%) with good glycogen index without M2-TONE treatment.
- Out the 42 cases that conceived after treatment with M2-TONE :- There was not a single abortion, there were no cases with any detectable congenital malformation. & there was a case of premature labour of 30 weeks gestation

Conclusion

M2-TONE seems to raise glycogen content in endometrium, help conception by its estrogenic activity.

Thus M2-TONE has beneficial effect on pregnancy and has no teratogenic effect on the foetus.

Endometrial scoring for prediction of implantationevaluation of drug therapy

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- The present paper describes the authors' experience of uterine scoring in the prediction of implantation, as well as an investigation into the effects of the non-hormonal, non-steroidal, Ayurvedic medicine M2-TONE on pregnancy rates with assisted reproductive techniques (ART)
- Study enrolled 40 female patients which were further divided into 4 groups,(10 patients each). One group each received M2-TONE, Spirulina, Vitamin C/E and placebo. ART procedure was performed to check the presence of pregnancy
- In a separate study, 32 patients were divided into 2 groups for studying improvement in blood flow to pelvic organs with M2-TONE in combination with aspirin (Group 1) or glyceryl trinitrate (GTN) (Group 2)
- It was observed that the highest endometrial thickness (9 mm), uterine score (18), and pregnancy rate (40%) were observed in the M2-TONE group
- The results indicate that a 'perfect' uterine score can successfully predict implantation (and hence pregnancy) in 75-85% of spontaneous (natural) and induced cycles
- Adjunctive therapy with M2-TONE, alone or in combination with aspirin or glyceryl trinitrate (GTN), appeared to enhance uterine score and, consequently, clinical pregnancy rates with ART

Conclusion

This study shows that administration of M2-TONE improves blood flow to the pelvic organs in patients undergoing ART, giving reasonable hope of success. Use of M2-TONE is justified in all cases of ART. It can be used with drugs such as aspirin and GTN.

Randomized placebo-controlled study to evaluate the role of M2-TONE as an adjuvant treatment in IUI protocol by assessing its effects on endometrial morphology, vasculature and pregnancy rate using 3 D Colour Doppler in female infertility.

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- The study was designed to compare the effectiveness of M2-TONE and placebo as an adjuvant in IUI protocol in improving endometrial receptivity as assessed by endometrial morphology, vascularity and pregnancy outcome in female infertility using the 3D Colour Doppler technique
- Fifty-five patients with anovulatory infertility were recruited. Twenty eight patients was administered Tablet M2-TONE and twenty seven patients were given placebo. Both drugs were given orally in the dose of 2 tablets twice a day for three months prior to the IUI procedure
- In M2-TONE group endometrial thickness increased to mean 8.65 mm from 4.6 mm at baseline (Day 2 of menstrual cycle) whereas in placebo group it rose to mean 6.89 mm from 4.8 mm at baseline. The decrease in the mean score of uterine artery blood flow impedance (Pulsatility index PI) was 1.13 in M2-TONE group and 0.72 in placebo group. The uterine score in the M2-TONE group increased significantly from 3.15 to 13.31 and from 3.16 to 10.08 in placebo group. There was corresponding increase in pregnancy rate in the M2-TONE group (30.77%) as compared to the placebo group (16.66%). Though there was slight increase in the serum estradiol and progesterone levels in M2-TONE group compared to the placebo group the difference was not statistically significant.

Conclusion

M2-TONE has shown better endometrial thickness, endometrial layering and better color flow to zone 3 of the endometrium compared to placebo. M2-TONE as an adjuvant treatment in IUI protocol showed significant improvement in pregnancy rate. This beneficial effect of M2-TONE can be attributed to improvement in the endometrial vascularity and morphology in the subjects probably by its modulating action on the hormonal status.

Evaluation of M2-Tone in menstrual disorders of adolescents and young adults.

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- The aim of this randomized blind placebo controlled study was to evaluate objectively, on multiple parameters, the effectiveness of M2-TONE syrup in the treatment of functional menstrual disorders in adolescents and young adult females
- Total 307 patients in 9 centers were enrolled in the study. 154 patients were put on M2-TONE syrup 1 tablespoon three times a day and 153 patients were on placebo syrup 1 tablespoon three times a day. This treatment was continued for 6 cycles
- The authors investigated parameters such as regularity of cycles, blood clots passed , amount of bleeding & associated pain
- It can be concluded from this trial that M2-TONE is clinically effective in the therapy of menstrual disorders in adolescents and young adult female patients

Conclusion

M2-TONE is considered to act through regulating the hypothalamus-pituitaryovarian hormonal balance. This will result in regularizing the menstrual cycle and the menstrual flow. The antispasmodic action of Twak, Baheda and Vacha are beneficial in relieving menstruation associated pain.

<u>Clinical Evaluation of M2-TONE in Adolescent Groups</u>

Dr. Preeti Dubey M.D., D.G.O.; Dr. Prasan R. Bhandari M. D. Department of Obstetrics and Gynaecology, G.S.V.M. Medical college Kanpur

- To evaluate the effect of a non-hormonal menstrual modulator (M2-TONE) with proven estrogenic activity in adolescent girls with commonly encountered menstrual complaints
- A randomized open study involving 111 girls aged between 11-19 years. Subjects complaining of the following menstrual disorders such as oligomenorrhoea, hypomenorrhoea, polymenorrhea, metrorrhagia, menorrhagia, irregular menses, dysfunctional uterine bleeding (D.U.B.), dysmenorrhoea were included
- Subjects were excluded from the trial if they had received any hormonal treatment in the preceding two months of the study. The patients were then put on tablet M2-TONE (two tablets) or syrup M2-TONE (two tablespoonfuls) three times a day for a period of 3 to 6 months. Regularity of menses (frequency and duration), pain, blood flow, investigators assessment, and patient satisfaction were evaluated
- Almost 80% of the patients were relieved of their symptoms within three months of treatment with M2-TONE, whereas the response rate increased to near 100% by the end of the 6-month study period
- In the investigators assessment for the improvement in the patient condition at the end of the study period on a 7-point scale, 94.6 % of the patients in the M2-TONE group showed a significant improvement in their condition
- The patients were asked to grade the relief obtained by them on an increasing scale of 10. At the end of the 3 month treatment period the average scale given by the patients was 7.68 while at the end of the six month period the patient satisfaction level had reached the level of 9.43, which indicates that the patients perceived M2-TONE as extremely effective in relieving their complaints

Conclusion

M2-TONE could be valuable and safe alternative to the conventional hormonal therapy in managing functional menstrual disorders of the adolescents.

Role of M2-TONE Syrup In Menstrual Disturbance ofReproductive Age Group Women

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- The study deals with "the role of a comprehensive herbomineral formulation M2-TONE syrup in menstrual disturbances of reproductive age group women
- An open and prospective type of clinical trial using M2-TONE syrup was done on 30 patients of reproductive age group at a dose of 2 teaspoonfuls 3 times daily followed up for a period of six months to one year. The clinical evaluation of symptoms and any side effects were noted every month during follow-up examination
- M2-TONE is an traditional Ayurvedic preparation being used for the treatment of common menstrual disorders
- With M2-TONE treatment 90% patients showed decrease in symptoms of their menstrual disorders mainly irregular menses and excessive menstrual bleeding within 6 months

Conclusion

M2-TONE acts by restoring a delicate balance between hormones, emotions and nutrition's.

M2-TONE is affective in the treatment of common menstrual disorders and has beneficial effects on general conditions of patients like improvement in sense of well being, decreased tiredness, increase hemoglobin levels.

Evaluation of M2-TONE syrup in functional menstrual <u>disorders</u>

Shashankv. Parulekar, Rashmi S. Parulekar. & Prasan R. Bhandari GS Medical College, KEM, Mumbai Published in: Int. Journal of Cuanecology Obstatrics India March Ar

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- The present study was designed to evaluate the effect of a non-hormonal menstrual modulator (M2-TONE) in commonly encountered functional menstrual disorders
- This was a randomized open study involving 100 female patients aged between 17 40 years. These patients were classified into 4 groups 25 in each based on their chief complaint:
 - Group A: Menorrhagia
 - Group B: Oligomenorrhoea
 - Group C: Secondary amenorrhoea
 - Group D: Irregular menstruation
- The patients were put on syrup M2-TONE one tablespoonful thrice daily for a period of 3 to 6 months. Regularity of menses (frequency and duration), pain, blood flow, investigators assessment, and patient satisfaction were evaluated
- With M2-TONE administration the overall success rate observed in different groups was menorrhagia (64%), oligomenorrheoa (72%), Secondary ammenorrhoea (60%) & Irregular menstruation (76%)

Conclusion

The results demonstrate the therapeutic efficacy of M2-TONE in the commonly encountered menstrual disorders.

It can be concluded that M2-TONE could be valuable and safe alternative to the conventional hormonal therapy in functional menstrual disorders.

Safety and efficacy of the M2-TONE in menstrual disorders

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- The study was designed to evaluate safety and efficacy of M2-TONE keeping in view the past experience with hormonal and other lines of treatment conventionally used
- 100 patients were studied at age group of 11 -50 years. Out of 100 patients 27 suffered from white discharge, 55 from menstrual problems,7 from dysmenorrheoa, 4 from sterility, 4 from delayed puberty & 3 from menopausal symptoms
- M2-TONE was administered at a dose of 2 tablespoon three times a day
- In the present study we observed that M2-TONE was very effective in 80% cases of Dysmenorrhoea, 60% cases of delayed puberty and 60% cases of menopausal symptoms within 3 cycles and 1 case of sterility (25%) became pregnant at the end of eight months of treatment

Conclusion

M2-TONE response seems encouraging in patients with irregular cycles, dysmenorrhoea, DUB, vaginal discharge, menopauses syndrome and raises hopes in sterility.