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अग्रवाल धर्मार्थ अस्पताल सोसाइटी (रजि०)

Aggarwal Dharmarth Hospital Society (Regd.)

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Regd. Under Directorate Health Service : Regn. No. 75
(Govt. of N.C.T. Delhi)

Ref. No.

Dated.. १०.८.२००८

**DOUBLE BLIND PLACEBO CONTROLLED TRIAL OF AN ANTI-DIABETIC
POLYHERBAL FORMULATION, AMREE PLUS CAPSULE FOR ITS EFFICACY &
SAFETY IN TYPE 2 DIABETES MELLITUS PATIENTS**

Diabetes Mellitus is a metabolic disorder characterized by hyperglycaemia and a disturbance in carbohydrates, fats and proteins metabolism. Incidence of Diabetes Mellitus has increased alarmingly during the past few decades and is apprehended to be a major health threat in the coming years.

Aim

The study was aimed to evaluate an anti-diabetic formulation Amree Plus Capsule for its efficacy and safety, since the available oral hypoglycaemic agents have several adverse effects and intolerance in long term.

Methodology

Double blind placebo controlled trial was conducted on 34 patients in the age group of 40-65 years of either sex for the duration of three months. Patients were selected from the OPD of Aggarwal Hospital, New Delhi.

The polyherbal formulation Amree Plus Capsule & placebo formulation were obtained from Aimil Pharmaceuticals (I) Ltd & distributed randomly among patients for adjudging their effects on blood glucose levels. Amree Plus Capsule contains several herbal components, which find mention in ancient Ayurvedic texts for Diabetes and have been safely used over centuries with promising results and safety in diabetic patients.


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Dosage

2 capsule twice a day.

Inclusion Criteria

Type 2 Diabetes Mellitus patients of atleast 5 years of diagnosis. Fasting blood glucose between 120 – 200 mg.% and post prandial blood glucose between 180-300 mg.%.

Exclusion Criteria

Patients with diabetic complications like neuropathy, nephropathy, retinopathy; severe infections, cardiac diseases, hypertension, any acute or chronic illness were excluded from the study.

Observation & Results

Out of 34 patients, 10 were females and 24 were males. Maximum cases were in the age group of 45-55 years.

The assessment of the results of the treatment was made on the basis of scoring of different clinical symptoms before and after treatment along with changes in blood sugar levels (FBS & PPBS). The change in symptoms of the disease under study was basically subjective, a change of more than 50% from the initial state was considered as significant. The most significant changes were observed for polyurea, polydypsia, tiredness, palpitation and anxiety.


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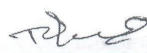
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Fasting & Post Prandial Blood Sugar before & after treatment.

Variable	No. of patients	Before Treatment	After Treatment
Fasting Blood Sugar			
Amree Plus Capsule	17	168.19 $\pm$ 5.99	124.2 $\pm$ 4.47
Placebo	17	157.68 $\pm$ 3.45	152.06 $\pm$ 5.44
Post Prandial Blood Sugar			
Amree Plus Capsule	17	218.4 $\pm$ 7.05	172.9 $\pm$ 6.25
Placebo	17	223.07 $\pm$ 7.91	212.83 $\pm$ 8.09

The data indicates highly significant decrease in blood glucose levels, thus establishing the anti-diabetic role of the polyherbal formulation Amree Plus Capsule. The formulation is also observed to be very effective in the management of different presenting symptoms of diabetes in the cases under study, which is indicative of its action towards the correcting the metabolic disturbances. The most important and striking observations of the study is that the blood sugar levels did not fall below the normal levels thus averting the possibility of episodes of the most dreaded adverse effect of OHGs i.e. hypoglycaemia. Another interesting feature that was observed during the continuation of therapy was that patient had a feeling of overall well-being, which is very important for a diabetic subject.


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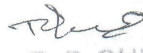
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Conclusion

Amree Plus Capsule, exhibited significant blood glucose lowering effect in diabetic patients without a single episode of hypoglycaemia. Moreover scientific study on its component herbs are suggestive of its efficacy. Amree plus Capsule therefore is concluded to be a safe and effective formulation for the management of Type 2 Diabetes Mellitus.

Amree Plus Capsule helps prevent / delay the related complications of diabetes mellitus by supplementing essential micro-nutrients, acting as a good restorative thus simultaneously working as a system toning formulation.


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