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Efficacy and Safety of an Oral Nutritional Supplement for Diabetes and Obesity in Pregnancy: A Phase 3 Randomized Controlled Trial

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Abstract:

Gestational Diabetes Mellitus (GDM) and obesity are one of the most common complications during pregnancy, contributing to significant risks in the mother and foetus. Indicated by carbohydrate intolerance, GDM can lead to complications for the mother and the foetus. Nutritional supplements with nutrients such as myo-inositol, omega-3 fatty acids, vitamin D, zinc, iron and folic acid can help in managing GDM and obesity, while preventing nutritional deficiencies during pregnancy. This multicentre, Double blind, Randomized comparative, Parallel Group, Placebo controlled Phase III Clinical trial evaluated the efficacy and safety of a nutritional supplement from British Biologicals Pvt Ltd, Pro PL Lite (Chocolate flavour) against a placebo powder in pregnant women with GDM and obesity. Over 6 weeks, 231 participants were recruited, with 200 completing the study. Results demonstrated that Pro-PL Lite achieved 99% and 98% efficacy in managing obesity and GDM, respectively, while showing optimal safety and tolerability. These findings support the use of the product for managing GDM and obesity in pregnant women.

Keywords: *Gestational Diabetes Mellitus, Diabetes, Supplements, Health, Diet*

I. INTRODUCTION:

Obesity has been on the rise over the past few years along with other metabolic disorders. Along with which, Gestational Diabetes (GDM) has become of the most prevalent complications during pregnancy, posing risks to the mother and the foetus. GDM is characterized by intolerance of carbohydrates or hyperglycaemia in the second or third trimester of pregnancy in women[6].

The prevalence of Gestational Diabetes Mellitus (GDM) varies between 7 to 28% at the global level[1], 10.1 to 20% in East and Southeast Asia[3], and 9 to 16% in India[2]. Causes of GDM include pre- conception obesity, metabolic disorders, Advanced maternal age, Family history of type 2 diabetes, excessive weight gain during pregnancy and sedentary lifestyle[5].

GDM can lead to short-term and long-term complications both in the mother and the foetus. Short-term complications include spontaneous abortions, preeclampsia, and an increased risk of C- sections in mothers. In the foetus, it can lead to neonatal hypoglycaemia, respiratory disorders, and increased mortality rates[4]. These risks indicate the need for glycaemic control during pregnancy which has been shown to improve birth outcomes in infants and reduction in complications.

Long-term effects include future development of type-2 diabetes, hypertension, obesity and cardiovascular disease in mothers and obesity, type- 2 diabetes and developmental delays in children. These can have lasting effects on the quality of life of both the mother and the child[6]. These long-term risks indicate the need for management strategies, glycaemic control and lifestyle interventions.

In controlling GDM, nutrition plays a significant role. The diet recommended for GDM includes sufficient macronutrients and micronutrients to support the development of the fetus and parallelly help in managing blood glucose levels and encourage optimal gestational weight gain[7]. A low carbohydrate, high protein and high fibre diet can help in management of GDM and reduce the risk of GDM. Energy requirements in GDM cases are recommended between 1500-2000 kcal/day or 30% calorie restriction for overweight or obese GDM women.

Carbohydrate ranges vary between 35 to 40% of total calories in the lower carbohydrate range to 50–60% in the moderate carbohydrate range. Fibre is recommended to be 28 grams per day and protein is recommended to be between 10-20% of the total calorie intake or 60 to 80 grams per day[8].

Furthermore, other nutrients like myoinositol and probiotics also help in managing GDM. Myoinositol has been found to reduce 50-60% of the incidence of GDM in high-risk pregnancies (obese, overweight, type-2 diabetes mellitus)[8]. Hence, a study was conducted using an oral nutritional supplement, Pro-PL Lite (Chocolate Flavour) from British Biologicals Pvt. Ltd., with a placebo to assess efficacy and safety in addressing GDM over a 6- week treatment period.

II. Methodology:

Study design: A multicentre, Double blind, Randomized comparative, Parallel Group, Placebo controlled Phase III Clinical trial to evaluate Efficacy and safety of Pro PL Lite (Chocolate Flavour) of British Biologicals with Placebo in Pregnancy and lactation, Overweight and obese pregnancy, Gestational Diabetes mellitus & pregnant women with family history of type 2 diabetes.

Participants:

Inclusion Criteria:

- Female population (Pregnant/lactating) ≥ 18 years of age.
- Pregnancy and lactation
- Overweight and obese pregnancy
- Gestational Diabetes mellitus or Pregnant women with family history of type 2 diabetes
- Patient ready to strictly adhere to protocol and sign informed consent form.

Exclusion Criteria:

- Patients with haematological disorders that compromise the surgical changes (e.g. myeloproliferative syndromes, anaemia Hb < 150,000 mm3)
- Patients with disorders of haemostasis (INR> I.40) (tTTPA> I.40)
- Patients with renal dysfunction (creatinine> 1.50)
- Have a JBS symptom severity score< 175 as defined by IBS-SSS.
- Patients with a history of allergy to Aluminium Hydroxide
- Confirmed clinical diagnosis of bile acid malabsorption and/ or on medication for bile acid malabsorption
- Infections (e.g. endocarditis, infection of immune human (HIV), hepatitis B and C, septicaemia and pneumonia)
- Recent history of current epilepsy, HIV infection, diabetes or cardiovascular
- Change of diet e.g. FODMAP, gluten-free within last 6 weeks.
- Use of acetylsalicylic acid is less than 5 days.
- History of chemotherapy (except for gestational conditions) of radiotherapy.
- Use of low molecular weight heparin for less than 24 hours.
- Have a malignant disease or any concomitant end-stage organ disease.
- Hypersensitivity to any trail product

Recruitment of participants:

231 were recruited, out of which 200 complied to the intake and 21 failed the screening and 10 failed to turn up for the follow-up. Mean age of the participants for the test and control group was 56.8 years. Participants were recruited after the initial screening including physical examinations or vital signs (body temperature, heart rate, respiratory rate and blood pressure), absence of tachycardia or disproportionate pulse rate either respect to insomnia and laboratory tests including Complete Blood Count (CBC), Erythrocyte Sedimentation Rate (ESR), Blood Culture, MRI, EEG, Serum creatinine, Blood Urea, Liver function tests including serum proteins, Serum electrolytes, Urinalysis and 12-lead Electrocardiogram.

Study period: The study was conducted from 20th October 2024 to 2nd December 2024 (Baseline, 1- week, 3-week and 6-week).

Informed Consent:

The informed consent forms were prepared in a non- technical and understandable language, in three languages i.e., English being the universal language, Hindi being national language and the local vernacular language (Telugu). It included information about of the patient's withdrawal and that there was no deprivation of the best possible treatment. On signing the consent form, the patient was included in the study.

Treatment:

Participants were randomized into two groups:

- **Test Group:** Pro-PL Lite (Chocolate Flavour) – 1.5 scoops (30g) twice daily in 100 ml lukewarm milk or water.
- **Control Group:** Placebo – 3 scoops (30 g) daily.

Outcome measures:

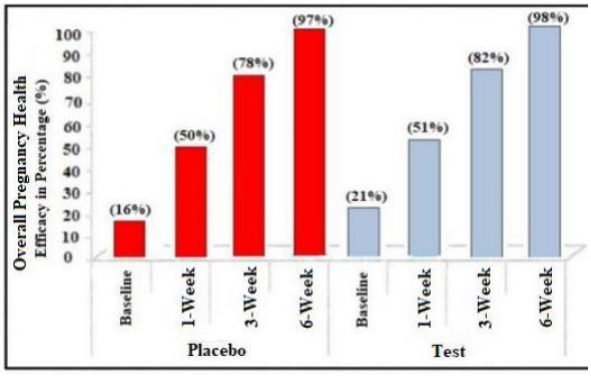
Efficacy: Efficacy of Pro PL Lite (Chocolate Flavour) of British Biologicals subscale of NAQ (Nutritional Assessment Questionnaire) from baseline to end of treatment (EOT) as compared to Placebo.

Safety: Safety of Pro PL Lite (Chocolate Flavour) of British Biologicals in Pregnancy and lactation, Overweight and obese pregnancy, Gestational Diabetes mellitus & pregnant women with family history of type 2 diabetes for period of 6 weeks from baseline to end of treatment as compared to Placebo.

III. Results:

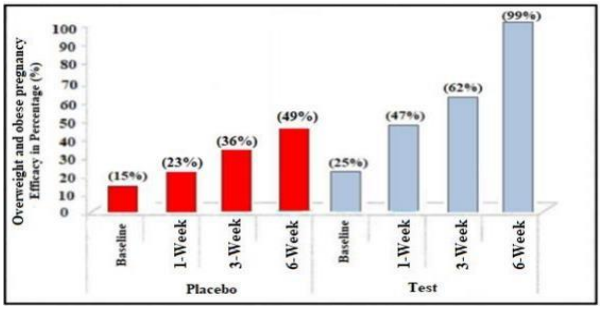
Efficacy assessment was done at baseline, 1 week, 3 week and 6 weeks for overall pregnancy health and treating symptoms (Overweight and obese pregnancy, (Gestational Diabetes mellitus/ family history of type 2 diabetes).

At baseline, the efficacy of the product in improving overall pregnancy health was 21% in comparison to 16% by the placebo. At the EOT, this proportion increased significantly to 98% in comparison to placebo which was 97% efficacious for Pregnancy health.

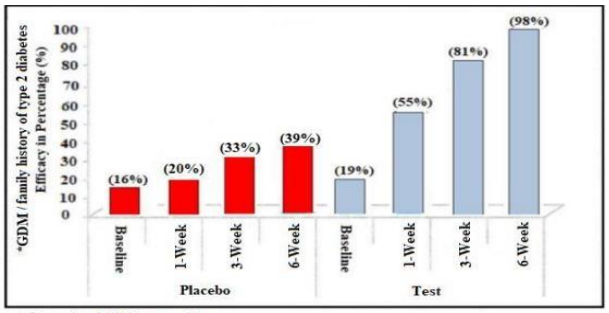


(Test: Pro PL Lite Chocolate Flavour; Reference: Placebo)

Furthermore, the test Product was 25% efficacious for treating overweight and obese pregnancy in comparison to Placebo which is 15% efficacious for treating it (Baseline). At the EOT, improvement was observed in cases of overweight and obese pregnancy with treatment of the test product and efficacy reached to 99% in comparison to Placebo which was 49% efficacious for treating overweight and obese pregnancy.



Additionally, the test product was 19% efficacious for treating Gestational Diabetes mellitus/ family history of type 2 diabetes in comparison to Placebo which is 16% efficacious for treating it at baseline. At the EOT, improvement was observed in cases of Gestational Diabetes mellitus/ family history of type
2 diabetes with treatment of the test drug and efficacy reached to 98% in comparison to Placebo which was 39% efficacious for treating the symptoms.



*Gestational Diabetes mellitus.

Overall, as per the participants, 93% cases from test group had good to excellent efficacy of treatment.

Assessment	Pro-Pl Lite (%)
Excellent	79%
Good	14%
Fair	7%
Very poor	--

Furthermore, overall, 91% cases from the test group had excellent tolerability to the treatment and no severe adverse events were reported throughout the trial, based on the tolerability scale used.

IV. Discussion:

At the end of the trial, the proportion of cases with better overall pregnancy health increased. The efficacy of the test product reached 98% in comparison to 97% of the placebo. A similar study on multiple-micronutrient supplementation with iron and folic acid for women during pregnancy had a positive impact on birth outcomes like reduction in LBW, reduction in SGA babies and preterm births[9]. Another study has concluded that supplementation of micronutrients like folate, iodine and iron can reduce adverse birth outcomes and improve a women's health during pregnancy[14]. Evidence also shows the need for supplements containing vitamin D, DHA, and iron to improve birth outcomes[15].

The prevalence of GDM has increased over the last decade[1] which has adverse effects on the mother and the child[4]. In the present study, we have used a test product with ingredients that help to manage GDM. The product was found have 98% efficacy in GDM cases as compared to 39% efficacy by the placebo. Studies have concluded that nutrients like myo- inositol, omega 3, vitamin E, vitamin D, choline, calcium, iodine and iron have beneficial effects in reducing chances of GDM and improving birth outcomes[10,11,16].

Obesity has risen over the last few decades, leading to an increase in obesity during pregnancy. Gestational obesity and overweight have been associated with adverse childbirth outcomes and maternal obesity can lead to long term adverse health outcomes in the offspring. Hence, weight management plays an important role before and during pregnancy[12]. In the present study, the test product was 99% efficacious in comparison to Placebo which was 49% efficacious for treating overweight and obese pregnancy. Studies have shown that pregnant women who consumed multiple micronutrient supplements (MMSs) during pregnancy had gained the recommended amount of weight[13].

V. Conclusion:

The present study was conducted to evaluate the safety and efficacy of Pro PL Lite (Chocolate Flavour) of British Biologicals Pvt. Ltd. with placebo among pregnant women with GDM, sub-optimal pregnancy health and obese or overweight pregnant women.

After 6 weeks of treatment with the product, there was a significant improvement in management of GDM, Obesity and overall pregnancy health. The safety results of the study demonstrated the product to be safe with no adverse effects and well tolerated when administered orally. Hence, Pro-pl lite offers an alternative for obese pregnant women and pregnant women with GDM.

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