3. NEED FOR THE STUDY

There are varieties of glucose-lowering agents available in the market for the treatment of T2DM with different mechanisms of action, although adverse effects, including the risk of hyperlipidemia and hypoglycemia are the main hindrances for the achievement of glycemic targets. Over a period of time, patients may become gradually less responsive to treatment with oral hypoglycemic agents because of worsening of their diabetic state. So it need to be worked on clinical study by monitoring clinical laboratory evaluations, including FBS, PPBS, HbA1c and lipid levels like LDL, HDL, TG, T-chol to determine the minimum effective dosage and to detect the blood glucose level lowering inadequately at the maximum suggested dosage or progressive decline in blood sugar control resulting an initial period of efficacy.

Literature suggests that, poly-herbal formulation has been encouraged as an alternative therapy to maintain T2DM complications. But in the monographs of oral anti-diabetic state that the interaction with poly-herbal products are not established. There are a few case reports or case series addressing herb-drug interaction studies. This indicates that, the scientific data collected regarding herb-drug interactions continue to be an antique part and remains as an unmet need in rationalizing the use of herbal drugs as related medications. So we thought of exploring the effect of herb-drug interactions and rationality of the use of herbs along with oral antidiabetic medications. Poly-herbal formulation (Mehagni) used in this study comprises of haridra, madhunasini, amalaki and ekanayakam, used as anti-diabetic drugs in T2DM. All these components of the poly-herbal formulation have proven anti-diabetic and anti-hyperlipidemia properties that help in reducing the complications of T2DM. Although commercially available poly-herbal formulation (Mehagni) is consumed by the patients with T2DM as an alternative therapy, its interaction with widely used anti-diabetic drug like GLB and GLM have not been evaluated so far. Herb-drug interactions which causing significant variations in the pharmacokinetics of either drug/s, antagonistic interactions may render the treatment ineffective and synergistic reactions may enhance the pharmacological response and sometimes may lead to toxicity, complicating dose, dosage regimen adjustment and individualization of therapy. Based on this a thorough search was conducted on the following drugs:-

a. Allopathic anti-diabetic drugs

   (I) Class of sulfonylurea drugs
   • Glibenclamide (GLB)
   • Glimepiride (GLM)

b. Poly-herbal anti-diabetic formulation
   • Mehagni