GLUCOCARE

GlucoCare Capsules in Impaired Glucose Tolerance:
An open, uncontrolled clinical study

INVESTIGATOR

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OBJECTIVES OF THE STUDY

To evaluate the clinical safety and efficacy of GlucoCare Capsules in the management of impaired glucose tolerance (IGT).

STUDY DESIGN

Open uncontrolled non-comparative clinical trial.

PRIMARY ENDPOINTS

Clinical recovery from symptoms of IGT like: Unusual thirst at night, Frequency of urination at night (>6-8 times), Tiredness, Unexplained weight loss.

Clinical recovery from fasting blood sugar (FBS) and postprandial blood sugar (PPBS) levels.

SECONDARY ENDPOINTS

Safety and toxicity profile of GlucoCare.

INCLUSION CRITERIA

- Adult patients of both sexes aged between 35 and 65 years
- Symptoms of IGT
- Willing to give written informed consent form.

EXCLUSION CRITERIA

- Insulin-dependent diabetes mellitus (IDDM - TYPE I)
- DM patients with acute complications of diabetes (Nephropathy, neuropathy, retinopathy and gangrene)
- Pregnant and lactating women
- Patients with malignant hypertension
- History of severe unstable angina
- Myocardial infarction,
- Cardiovascular accidents,
- Renal failure,
- Unwilling to give written informed consent form

COMPOSITION

Each GlucoCare capsule contains:

ACTIVE INGREDIENTS	QUANTITY
Commiphora wightii	7.5 mg
Shilajeet (Purified)	7.5 mg
Gymnema sylvestre	35 mg
Pterocarpus marsupium	30 mg
Glycyrrhiza glabra	20 mg
Casearia esculenta	25 mg
Syzygium cumini	23 mg
Asparagus racemosus	20 mg
Boerhaavia diffusa	20 mg
Sphaeranthus indicus	10 mg
Tinospora cordifolia	10 mg
Tribulus terrestris	10 mg
Phyllanthus amarus	10 mg
Gmelina arborea	10 mg
Gossypium herbaceum	10 mg
Aloe vera	5 mg
Triphala	8 mg
Momordica charantia	10 mg
Piper nigrum	2.5 mg
Ocimum santum	2.5 mg
Abutilon indicum	2.5 mg
Curcuma longa	2.5 mg
Rumex maritimus	2 mg
Trikatu	2 mg

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METHODOLOGY

Twenty patients of IGT attending the outpatient Department of Medicine, Calcutta Medical College, Kolkata, India were included in the study and were put on GlucoCare. Patients' entry characteristics are mentioned in the following table.

Table 1

ENTRY CHARACTERISTICS

PARAMETERS	GLUCOCARE
Mean age (years) (Mean ± SD)	38.00 ± 8.50
Mean weight (kg) (Mean ± SD)	58.50 ± 10.20
Sex ratio (M:F)	12:8
Unusual thirst at night	19
Frequency of urination at night (>6-8 times)	16
Tiredness	16
Unexplained weight loss	18
Fasting blood sugar (>140mg%)	18
Post prandial blood sugar (>180mg%)	19

All the patients received GlucoCare at a dose of 2 capsules twice daily, before meals for 3 months. Patients underwent clinical examination on entry and at monthly intervals for 3 months. Adverse effects if any were noted down. The protocol of the study was approved by the hospital's Ethics Committee and the patients were free to withdraw from the study if they so desired. No other medication was allowed for these patients. The patients were asked to return for follow-up every month till the end of the study period.

STATISTICAL ANALYSIS

Results were analyzed statistically using student's 't' test.

RESULTS

All the patients showed significant improvement in their symptoms from the 1st month onwards and this continued till the end of the study.

Table 2

EFFECT OF DRUG THERAPY ON SYMPTOMS IGT

PARAMETER (No. of patients with)	GLUCOCARE			
	AT ENTRY	1ST MONTH	2ND MONTH	3RD MONTH
Unusual thirst at night	19	17	12	4*
Frequency of urination at night (>6-8 times)	16	14	11	4*
Tiredness	16	12	8	3*
Unexplained weight loss	18	14	6	3*

**p<0.05 as compared to respective "At entry" values*

Table 3

EFFECT OF DRUG THERAPY ON BLOOD SUGAR LEVELS

PARAMETER (No. of patients with)	GLUCOCARE			
	AT ENTRY	1ST MONTH	2ND MONTH	3RD MONTH
Fasting blood sugar (mg%)	162 ± 16	148 ± 18	130 ± 10*	128 ± 16
Post-prandial blood sugar (mg%)	192 ± 30	179 ± 18	161 ± 12*	152 ± 13*

**p<0.05 as compared to respective "At entry" values*

The results indicate that GlucoCare significantly decreased most of the symptoms of IGT, including unusual thirst at night, frequency of urination at night, tiredness, and weight loss. GlucoCare was also seen to reduce the FBS and PPBS levels from 2nd month onwards and continued to improve further till the end of the study. Overall improvement was seen by 3rd month in most of the patients (Table 4).

Table 4

OVERALL RESPONSE TO TREATMENT AT 3RD MONTH

PARAMETER		GLUCOCARE (n=20)	
		NO. OF PATIENTS	RESPONSE (%)
Symptom-free		17/20	85%
Patient's impression	Good	16/20	80%
	No response	4/20	20%

**p<0.05 as compared to respective "At entry" values*
Drop outs: Nil.

Overall response to treatment was assessed by interviewing the patients at the end of study period. Seventeen out of 20 patients were symptom-free by 3rd month and 16 of them felt that they had good response to the treatment.

ADVERSE EFFECTS: GlucoCare Capsules were well tolerated by all the patients throughout the treatment period without any incidence of adverse effects.

DISCUSSION

Impaired glucose tolerance (IGT) and impaired fasting glucose (IFG) form an intermediate stage in the natural history of diabetes mellitus. Approximately 10-15% percent of adults have one of these conditions. Impaired glucose tolerance is defined as two-hour glucose levels of 140-199 mg/dL (7.8-11.0 mmol) on the 75-g oral glucose tolerance test, and IFG is defined as glucose levels of 100-125 mg/dL (5.6-6.9 mmol per L) in fasting patients. These glucose levels are above normal but below the level that is diagnostic for diabetes. Patients with IGT or IFG have a significant risk of developing diabetes and thus are an important target group for primary prevention..

Control of blood sugar on a 24 hour basis is the desired goal in the management of diabetes mellitus, so as to prevent or delay the onset of secondary complications of diabetes mellitus. Several hypoglycaemic agents available for clinical use are associated with a characteristic profile of side-effects and failures. With each year of treatment, about 3-5% of patients with NIDDM who have achieved acceptable or better glycaemic control are said to lose their responsiveness to sulphonylureas.

GlucoCare produced significant reduction in both fasting and postprandial blood sugar levels. All the patients reported a sense of well being and no side-effect was reported.

Crude components extracted from the leaves of Gymnema sylvestre are one of the triterpene saponins that suppress the sweetness by a reversible effect on the sweet taste receptors. Pharmacological tests also show reduction in the blood sugar. The extract suppresses the increment of the blood glucose by inhibiting the reuptake in the intestines (Shimizu et al., 1997).

Pterocarpus marsupium can control the diabetic related metabolic alterations apart from controlling the glucose levels (Dhanabal et al., 2006). Its hypoglycemic action may be due to its reduced glucose absorption from the gastrointestinal tract (Vats et al., 2002). One of the clinical trials shows that oral intake of Pterocarpus marsupium extract has potent hypoglycemic activity (both fasting and postprandial) that can be comparable with the Tolbutamide (Hariharan et al., 2005).

On the basis of the above observations, it can be concluded that GlucoCare may elicit its hypoglycaemic action by enhancing insulin release from pancreatic B islets and also accelerate glucose uptake and peripheral glucose utilising processes. This lends credence to the use of GlucoCare Capsules as a potent anti diabetic.

The present clinical study involving 20 patients suffering from IGT indicates that GlucoCare has beneficial effects in relieving the symptoms and bringing about overall improvement. The results also indicate that GlucoCare reduces the levels of FBS and PPBS. Besides, a majority of patients (16/20) evaluated in this trial reported excellent response to treatment.

CONCLUSION

The present clinical study indicates significant clinical efficacy of GlucoCare Capsules in the management of IGT. This formulation is well tolerated and safe in the dose used.