La Renon

LOBULA 0.5

Lobeglitazone Sulfate Tablets 0.5 mg

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EFFICACY AND SAFETY OF LOBEGLITAZONE MONOTHERAPY IN PATIENTS WITH TYPE 2 DIABETES MELLITUS OVER 24-WEEKS: A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, PLACEBO CONTROLLED TRIAL

Type of study: multicenter, randomized, double-blind, parallel-group, placebo controlled study

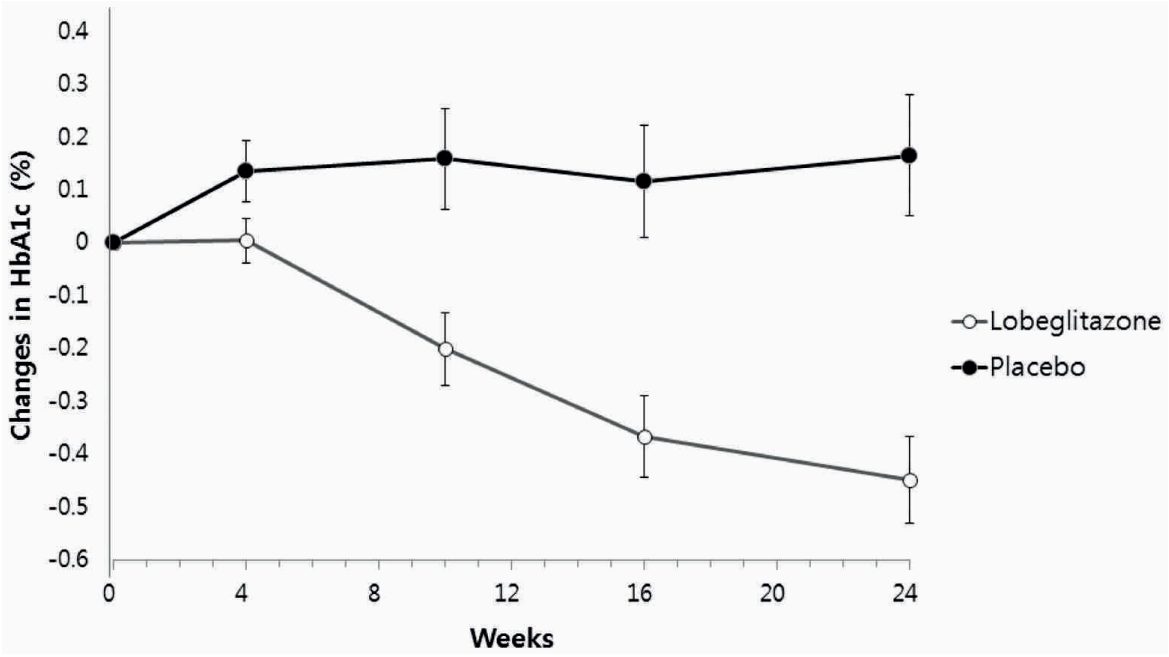
Subjects: 173 patients with type 2 diabetes.

Dose: lobeglitazone 0.5 mg (n=115) with placebo (n=58)

Duration: 24 weeks

Outcomes:

- At 24 weeks, **a significant reduction in HbA1c** was observed with **lobeglitazone** versus placebo (-0.44% vs 0.16%, mean difference -0.6%, p<0.0001).
- The goal of HbA1c <7% was achieved **significantly more in the lobeglitazone group** compared to the placebo group (44% vs 12%, p<0.0001).
- Markers of insulin resistance were also **improved in the lobeglitazone group**.
- Lobeglitazone treatment significantly improved triglycerides, high density lipoprotein cholesterol, small dense low density lipoprotein cholesterol, free fatty acid, and apolipoprotein-B/CIII compared to placebo (p<0.01, respectively).
- The safety profile was comparable between the two groups and lobeglitazone was well tolerated.



Conclusion: Lobeglitazone 0.5 mg showed **a favorable balance in the efficacy and safety profile.** The results support a potential role of lobeglitazone in treating type 2 diabetes.

Reference: PLoS One. 2014 Apr 15;9(4):e92843.

SAFETY AND EFFICACY OF LOBEGLITAZONE MONOTHERAPY IN PATIENTS WITH TYPE 2 DIABETES MELLITUS OVER 52 WEEKS: AN OPEN-LABEL EXTENSION STUDY

Type of study: This multicenter, randomized, controlled, parallel-group, 52-week study consisted of a 24-week, double-blinded study followed by a 28-week, open-labeled extension study.

Subjects: 173 patients with type 2 diabetes.

Dose: Lobeglitazone 0.5 mg (n = 115) or matching placebo (n = 58).

Duration: 52 weeks

Outcomes:

- The mean HbA1c (7.26% (56 mmol/mol) vs. 8.01% (64 mmol/mol), p = 0.004) was significantly lower in Group M, compared with Group S at the beginning of the extension period.
- Final HbA1c decreased after switching to lobeglitazone during the extension period (-0.53%, p< 0.001). The proportion of patients with HbA1c <7.0% (53 mmol/mol) at 52 weeks was greater in group M but was not significantly different since the two groups received lobeglitazone (group M: 46.8% vs. group S: 37.9%; p = 0.421).

HbA1c (%)	Group M (n=64)		Group S (n=29)		p-Value[b]
	Mean (SD)	p-Value[a]	Mean (SD)	p-Value[a]	
Baseline	7.79 (0.83)		8.00 (0.68)		
Week 24	7.26 (1.25)	<0.001*	8.01 (0.94)	0.957	0.005*
Week 52	7.30 (1.29)		7.48 (0.94)		
Change from baseline	-0.50 (1.14)	<0.001*	-0.52 (0.81)	0.002*	0.904
Change from week 24			-0.53 (0.74)	<0.001*	

a- Differences from baseline at each time point were assessed using paired t-test.
b- Treatment group differences were analyzed using Student's t-test or ANCOVA.
*-p-Value <0.05 was considered statistically significant.
Group M-The participants who were randomly assigned to receive lobeglitazone at baseline maintained the treatment for the entire 52 week
Group S-The patients with placebo were switched to lobeglitazone 0.5 mg during the extension.

Conclusion: This study demonstrated that statistically significant improvements observed in glycemic control after a 24-week treatment with lobeglitazone were maintained over the 52-week. Moreover, lobeglitazone improved the markers of insulin resistance and β cell function and also showed beneficial effect in lipid profile.

Reference: Diabetes research and clinical practice. 2015 Dec 1;110(3):e27-30.

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DESCRIPTION:

Lobeglitazone is a novel thiazolidinedione with potent efficacy and a favorable safety profile.

INDICATION:

Indicated for treatment of adult type 2 diabetes mellitus patients:

- Who are inadequately controlled by diet and exercise for whom metformin is inappropriate because of contraindications or intolerance (as monotherapy).
- Who are inadequately controlled by diet and exercise for whom metformin despite maximal tolerated dose of metformin monotherapy (as dual oral therapy in combination).
- Who are inadequately controlled by diet and exercise and taking a sulphonyl urea at maximal tolerated dose of sulphonyl urea monotherapy in which metformin is inappropriate because of contraindications or intolerance (as dual oral therapy in combination).

MECHANISM OF ACTION:

- Lobeglitazone acts as an insulin sensitizer by binding and activating Peroxisome Proliferator-Activated Receptors (PPAR) gamma within fat cells.
- By promoting the binding of insulin at fat cells, lobeglitazone has been shown to reduce blood sugar levels, lower hemoglobain A1C (HbA1C) levels, and improve lipid and liver profiles.

DOSAGE AND ADMINISTRATION:

- One tablet once daily or as directed by the Physician.
- Patients with hepatic impairment: At the beginning of treatment, if the patient shows clinical evidence of active liver disease or increased serum transaminase levels (more than 2.5 times the upper limit of ALT or AST), therapy with this drug should not be initiated.
- Patients with renal impairment: Dosage adjustment is not necessary for patients with mild to moderate renal impairment.

PRESENTATION:

LOBULA 0.5: Available as 10 tablets in a strip.

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