IRIS:
Main Results of the Insulin Resistance Intervention After Stroke Trial

Purpose: This study evaluates pioglitazone, a PPAR-ϒ agonist and insulin sensitizing drug, for secondary stroke prevention in patients with insulin resistance and a recent ischemic stroke or transient ischemic attach (TIA).

Trial Design: Interventional, randomized, international, multicenter, efficacy trial; phase 3; pioglitazone vs. placebo. Pioglitazone was started at 15 mg and increased to 45mg/day over 12 weeks. Patients were without diabetes but were insulin resistant, were 40 years of age or older, and had an ischemic stroke or TIA within the last 6 months. Average follow-up time = 4.8 years. N=3876

Primary Endpoint: fatal or non-fatal stroke or MI.

Secondary: Stroke; Acute Coronary Syndrome; Stroke, MI, HF; DM; Cognitive Decline; Mortality

Trial Results	pioglitazone	placebo	P value
fatal or non-fatal stroke or MI – primary endpoint	9%	11.8%	0.007
DM	3.8%	7.7%	<0.0001
Non-serious Adverse Events	2.6 kg	- 0.5 kg	<0.01
Serious Adverse Events: Bone Fracture	5.1%	3.2%	<0.01

Conclusions: Targeting insulin resistance with pioglitazone in this study resulted in a reduction of secondary stroke and myocardial infarction. There was more weight gain and a greater risk for fractures with pioglitazone.

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