ZYCHROME®

RESEARCH OVERVIEW

Zychrome® is a unique, patent-pending chromium (Cr) complex consisting of chromium, niacin and L-cysteine (chromium dinicocysteinate). More than 12 different chromium complexes were screened in preclinical studies in order to derive at the most efficacious complex. *In vitro* and *in vivo* studies demonstrated that Zychrome is more efficacious than other forms of chromium in decreasing fasting glucose levels, glycated hemoglobin levels (HbA1c), insulin levels and vascular inflammation as assessed by CRP, MCP-1, ICAM-1 and oxidative stress levels.[1] These effects of Zychrome are mediated via the regulation of cell signal transduction pathways associated with insulin function, glucose control and vascular inflammation.[1]

A randomized, double-blind, placebo-controlled clinical study showed that Zychrome significantly modulated the levels of insulin and insulin resistance as well as the inflammatory cytokine TNF-α and oxidative stress marker protein carbonyl.[2] Toxicological studies have demonstrated a wide margin of safety[3] and Zychrome has been determined GRAS.[4]

Summary of Zychrome® Clinical data – 83 Subject Study[2]

Study Design

- Study was conducted at the Health Sciences Center-Shreveport, Louisiana State University.
- Seventy-four subjects who completed the trial took either placebo (n=25), Zychrome (400 mcg Cr/day; n=24) or chromium picolinate (400 mcg Cr/day; n=25) for three months.
- Nine subjects were lost to follow up. Their data was not analyzed as per the pre-defined condition in the study protocol.
- All subjects continued to receive the usual standard of care for diabetes throughout the study period.
- All study evaluations were done at baseline, and after one, two, and three months post-supplementation.

Study Outcomes

- Zychrome significantly reduced fasting insulin levels at three months resulting in a 30% reduction (p=0.01).
- Zychrome significantly reduced insulin resistance, as measured by the homeostatic model assessment (HOMA), resulting in a 30% reduction (p=0.02) compared to baseline.
- Zychrome significantly reduced levels of the inflammatory cytokine TNF-α by 21% (p=0.01) compared to baseline.
- Zychrome significantly reduced the oxidative stress marker protein carbonyl by 10% (p=0.02) compared to baseline.
- No significant change was seen in insulin levels, insulin resistance, TNF-α and protein carbonyl levels in chromium picolinate or placebo group compared to baseline values.

Safety Conclusion

- No major advere events reported during the study.
- The minor adverse events observed were evenly distributed between the groups.

Summary of Zychrome® Preclinical Research[1]

In vitro and *in vivo* studies demonstrate that Zychrome significantly improves markers of glycemia, oxidative stress and inflammation as follows:

- Zychrome significantly reduced the circulating levels of blood glucose and HbA1c in Zucker Diabetic Fatty (ZDF) rats ($p<0.05$).
- Zychrome significantly lowered the vascular inflammation markers, MCP-1, CRP, and ICAM-1 ($p<0.05$), which are known to be directly associated with insulin resistance.
- Zychrome significantly increased vitamin C levels ($p<0.05$). Vitamin C lowers oxidative stress and markers of vascular inflammation, thus helping to decrease insulin resistance.
- Zychrome also significantly increased adiponectin levels ($p<0.05$). Adiponectin has potent insulin sensitizing activity and regulates blood sugar and energy mainly by decreasing inflammatory markers levels ($p<0.05$). Adiponectin has potent insulin sensitizing activity and regulates blood sugar and energy mainly by decreasing inflammatory markers.
- Zychrome restored GLUT-2/IRS-1 balance. IRS-1 is the major substrate of insulin receptor kinase that activates glucose transport into cells. Bringing this pathway to a normalized state decreases glucose levels. Zychrome decreased NF□B and Akt levels, which activate the insulin resistance cascade.

Conclusions

- *In vitro* and *in vivo* studies show that Zychrome is efficacious in decreasing blood glucose, HbA1c, vascular inflammation markers and oxidative stress levels in ZDF rats, a model of type 2 diabetes.
- Clinical study substantiates that Zychrome is an effective and safe chromium complex for modulating insulin levels and function.
- TNF-α and protein carbonyl are important markers associated with type 2 diabetes. Zychrome significantly reduced the levels of these markers, which may help to lower insulin levels and insulin resistance.
- Zychrome's onset of action appears to be rapid (within three months of supplementation).

Recommended Use

Take 400 mcg of Zychrome daily with a meal.

1. Jain SK, Croad JL, Velusamy T, Rains JL, Bull R. Chromium dinicocysteinate supplementation can lower blood glucose, CRP, MCP-1, ICAM-1, creatinine, apparently mediated by elevated blood vitamin C and adiponectin and inhibition of NF-κB, Akt, and Glut -2 in livers of zucker diabetic fatty rats. *Mol Nutr Food Res*. 2010;54:1-10.
2. Jain SK, Kahlon G, Moorehead L, et al. The effect of chromium dinicocysteinate supplementation on circulating levels of insulin, TNF-α, oxidative stress and insulin resistance in type 2 diabetic patients: Randomized, double-blind, placebo-controlled clinical study. *Mol Nutr Food Res*. 2012;56:1333-1341.
3. Sreejayan N, Marone PA, Lau FC, Yasmin T, Bagchi M, Bagchi D. Safety and toxicological evaluation of a novel chromium(III) dinicocysteinate complex. *Toxicol Mech Meth*. 2010;20:321-333.
4. Burdock Group. Dossier in Support of the Generally Recognized as Safe (GRAS) Status of Chromium (III) Dinicocysteinate Complex (Zychrome®) As a Food Ingredient. Internal data, 2012.