

A Pilot Clinical Study of a Nutraceutical Formulation in Overweight Subjects

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Type-2 Diabetes

- Type 2 diabetes mellitus (T2DM) is growing at epidemic proportions
 - ~350 million people worldwide
 - ~30 million in the U.S.
- Diabetes is an independent risk factor for cardiovascular disease (CVD)
 - Leading cause of morbidity and mortality in the United States

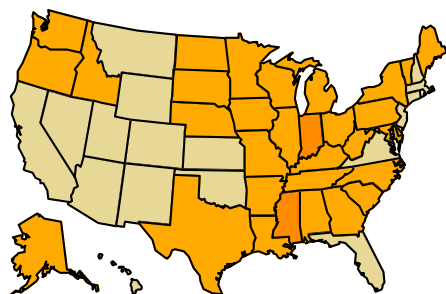
Type-2 Diabetes and the Obesity Connection

- In the US about 2/3rd of the adult population is either overweight or obese
- Growing epidemic of obesity is one of the reasons for increased prevalence of diabetes
- Number of children and adolescents with obesity and diabetes is on the rise

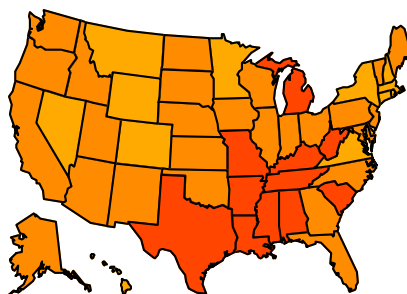
Age-Adjusted Prevalence of Obesity and Diagnosed Diabetes Among U.S. Adults Aged 18 Years or older

Obesity (BMI ≥ 30 kg/m²)

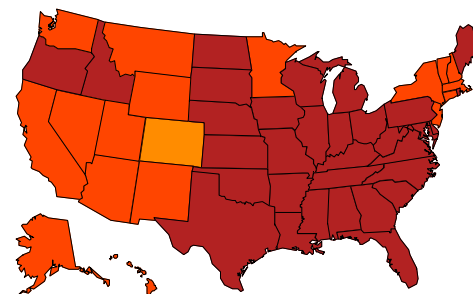
1994



2000



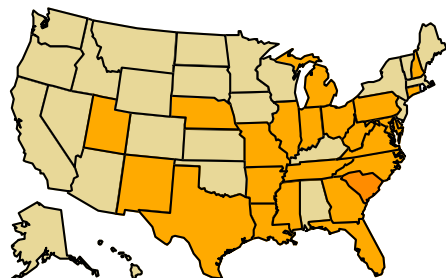
2010



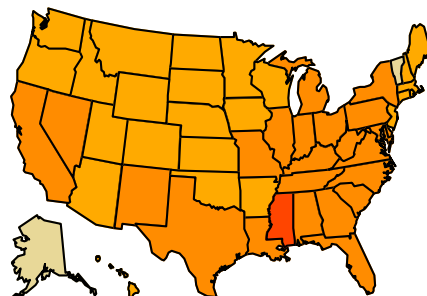
No Data
 <14.0%
 14.0-17.9%
 18.0-21.9%
 22.0-25.9%
 $\geq 26.0\%$

Diabetes

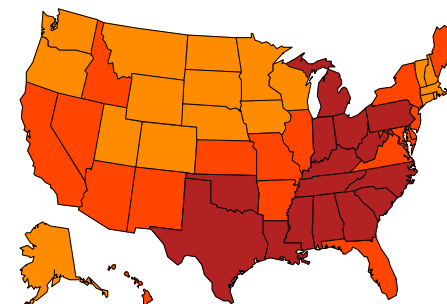
1994



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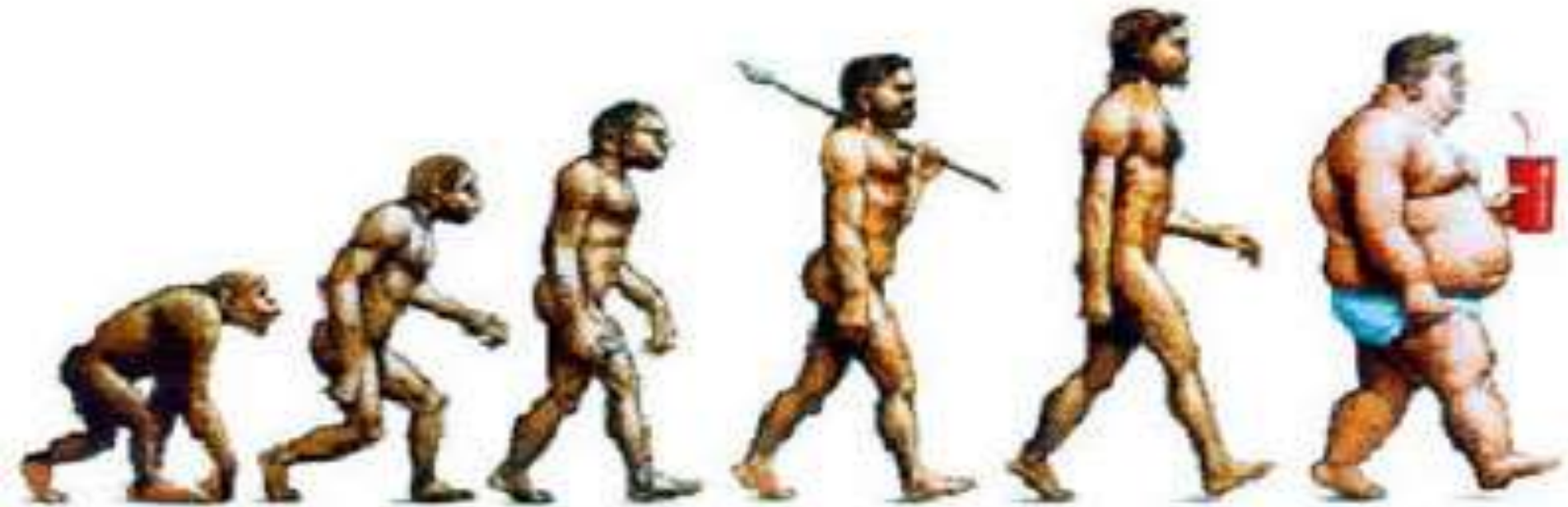
No Data
 <4.5%
 4.5-5.9%
 6.0-7.4%
 7.5-8.9%
 $\geq 9.0\%$

CDC's Division of Diabetes Translation. National Diabetes Surveillance System available at <http://www.cdc.gov/diabetes/statistics>

Insulin Resistance

- Impaired cellular response to insulin
- Prediabetic stage
- Precedes the development of full-blown type 2 diabetes
- Often is seen during transition from obesity to type-2 diabetes

Diet?



24
HOUR

FITNESS



POINT LOU
HANDICAP
TO UPPER
LEVELS
LOCATED
24 HOURS

SPECIALTY
HEALTHY SNACKS
& DRINKS
EVERY DAY
10:00

SPECIALTY
HEALTHY SNACKS
& DRINKS
EVERY DAY
10:00



Insulin Resistance

- **Management:**

- Diet (Therapeutic Life Style Modification)
- Exercise
- Pharmacotherapy
- Nutritional supplements

GlyacaCare™ Plus

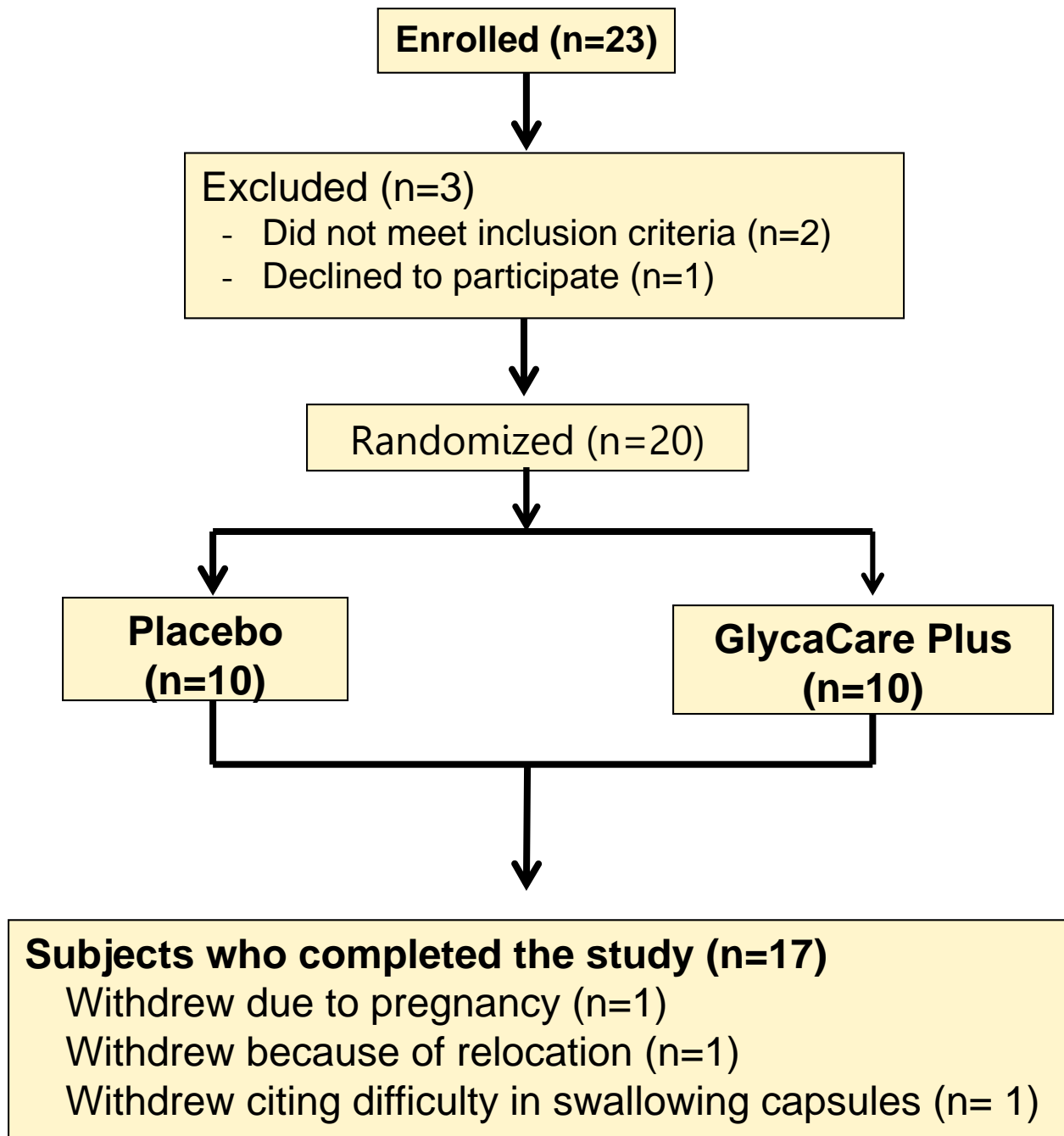
- Formulation containing:
 - Cinnamon extract
 - Piperine
 - *Pterocarpus marsuipum* extract
 - Zinc monomethionine
 - Copper lysinate
 - Chromium polynicotinate
 - Bismaltoxo-vanadium

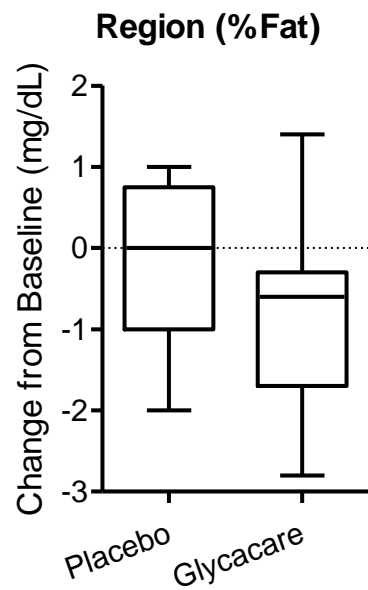
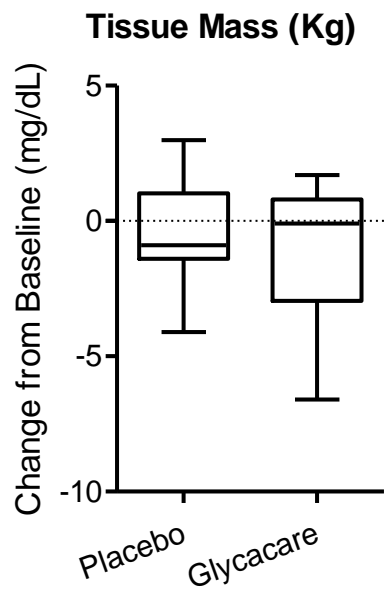
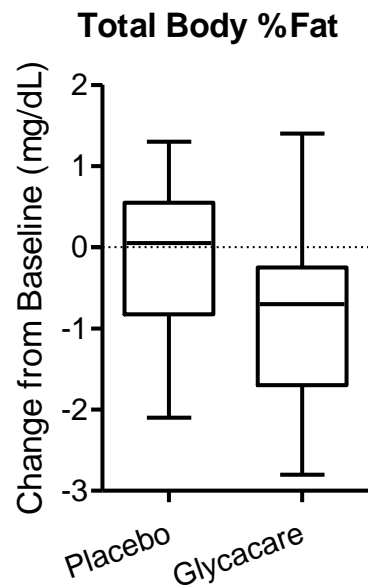
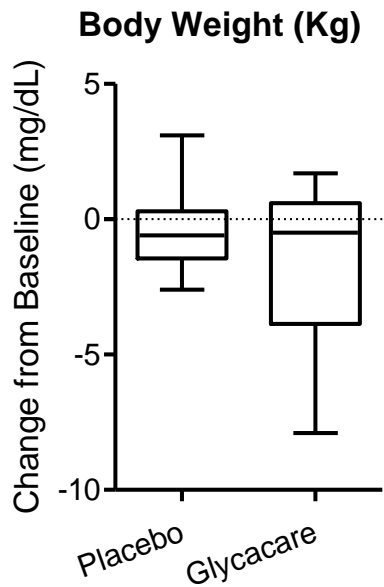
Objective

- To determine the efficacy of the formulation to
 - Improve insulin sensitivity and glucose tolerance in overweight adults
 - Reduce oxidative stress and inflammatory markers

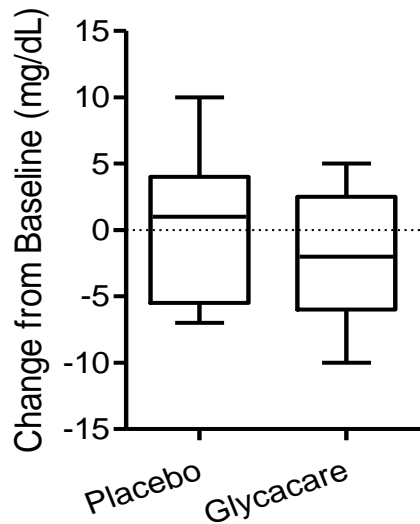
Design

- Randomized, double-blind, placebo-controlled study
- 12-week intervention
- Inclusion criteria:
 - Body mass index (BMI) between 25-40 kg/m²
 - Not diabetic, not pregnant, does not have any other chronic disease

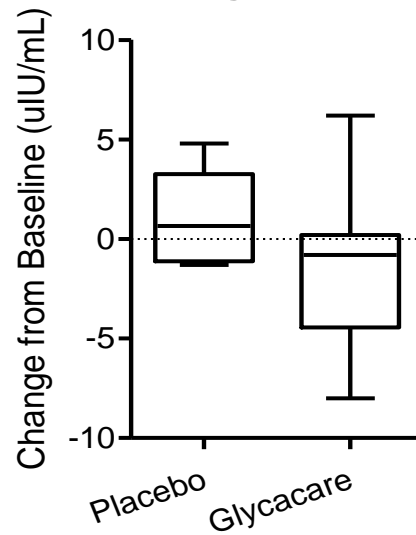




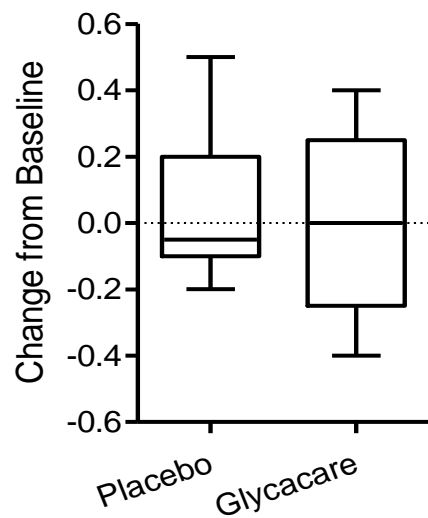
Fasting Glucose



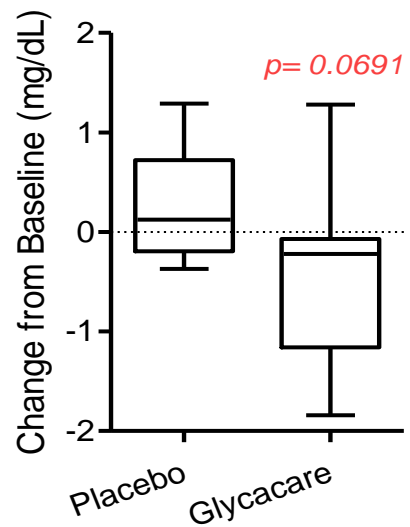
Fasting Insulin

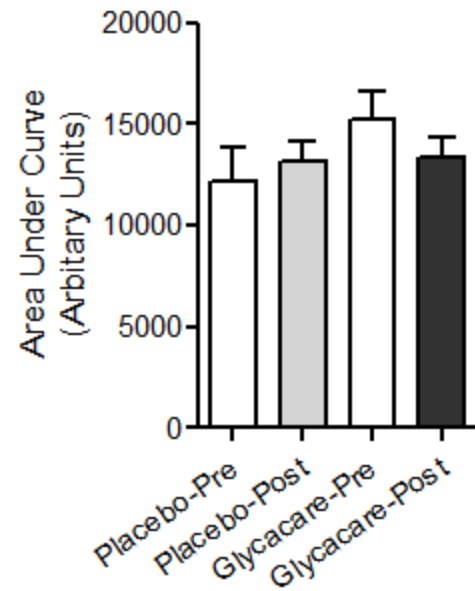
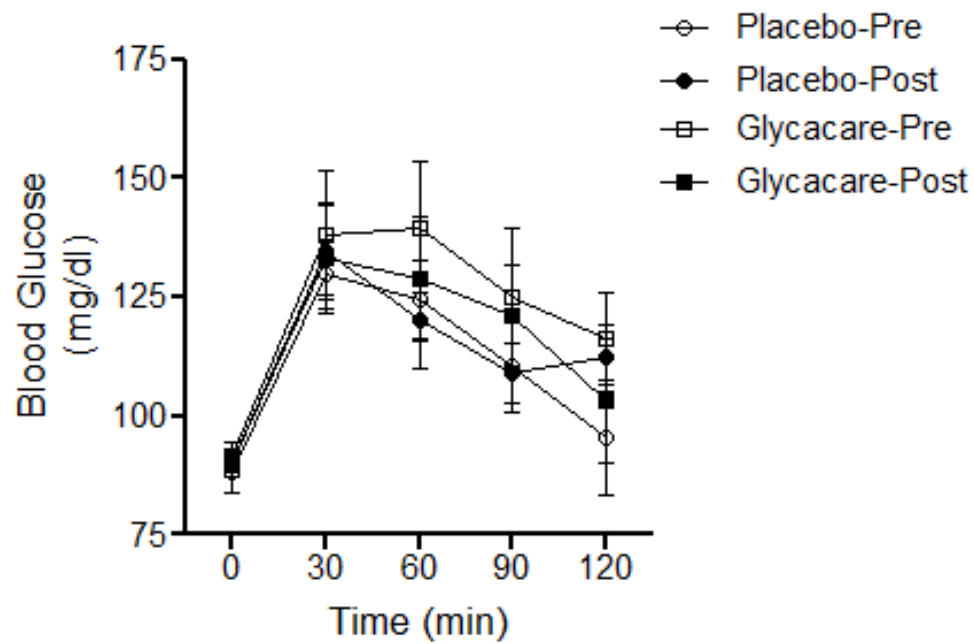


Hemoglobin A1c

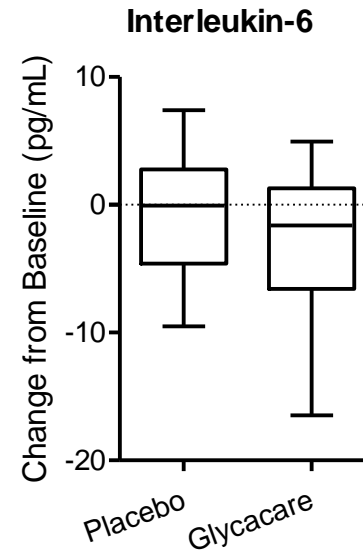
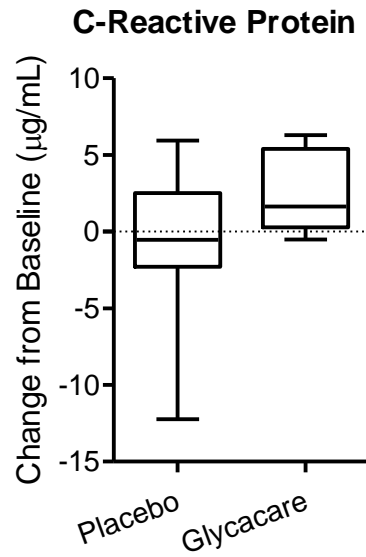


HOMA-IR

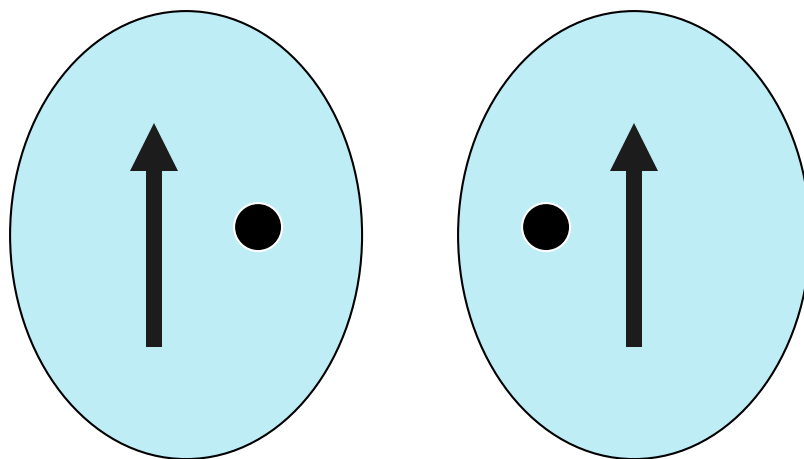




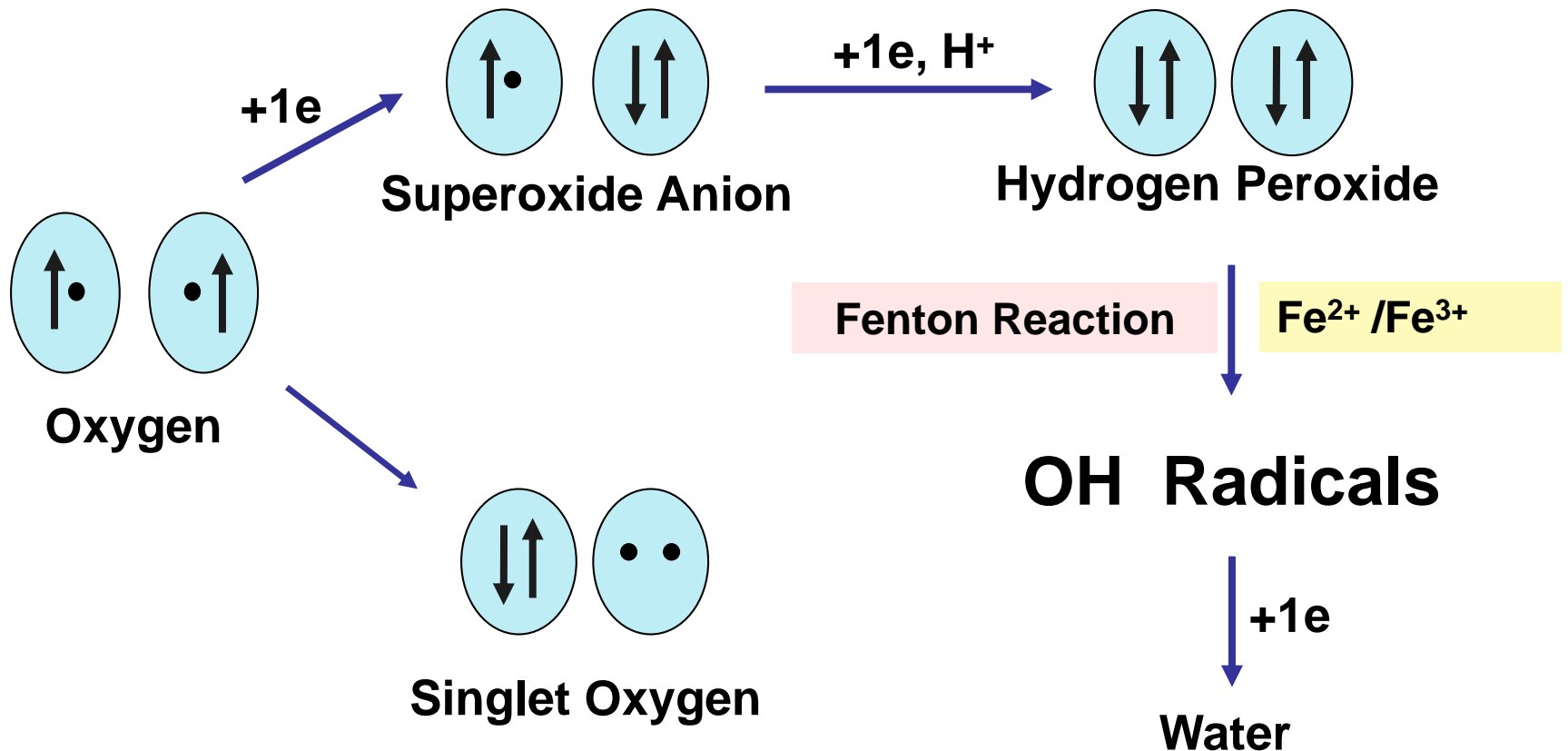
Inflammatory Markers



Molecular Oxygen- A Biradical



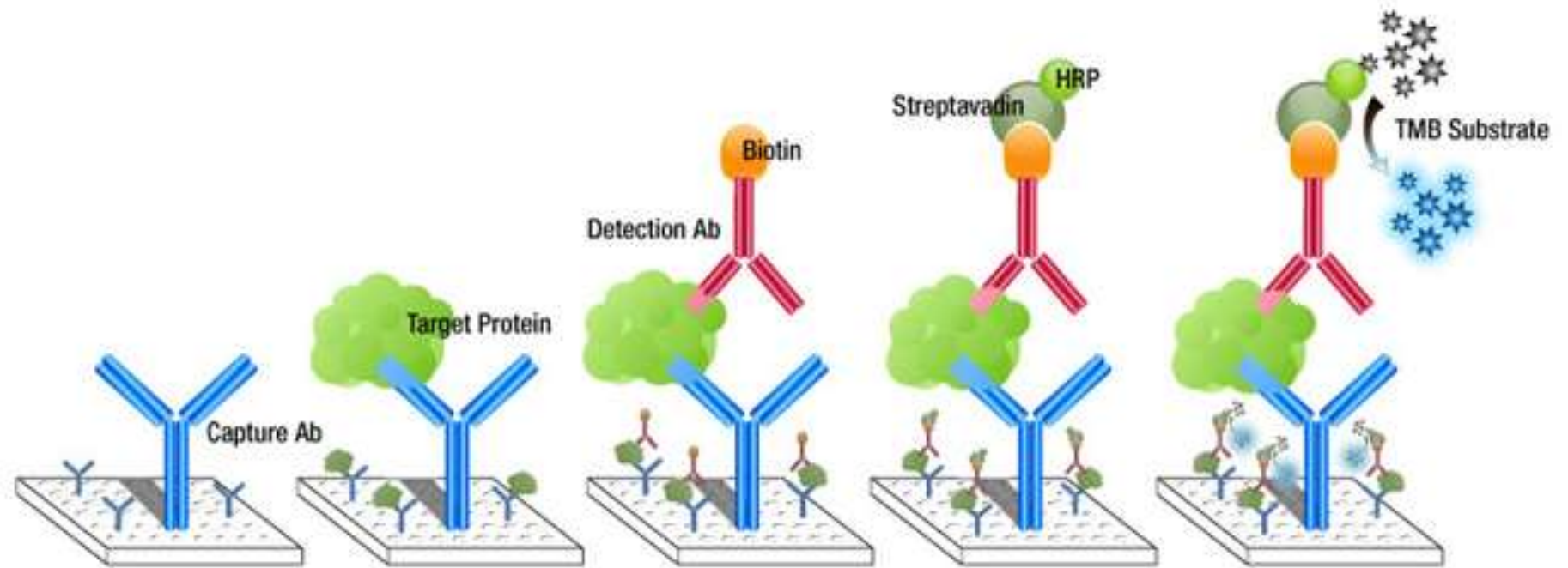
Reactive Oxygen Species



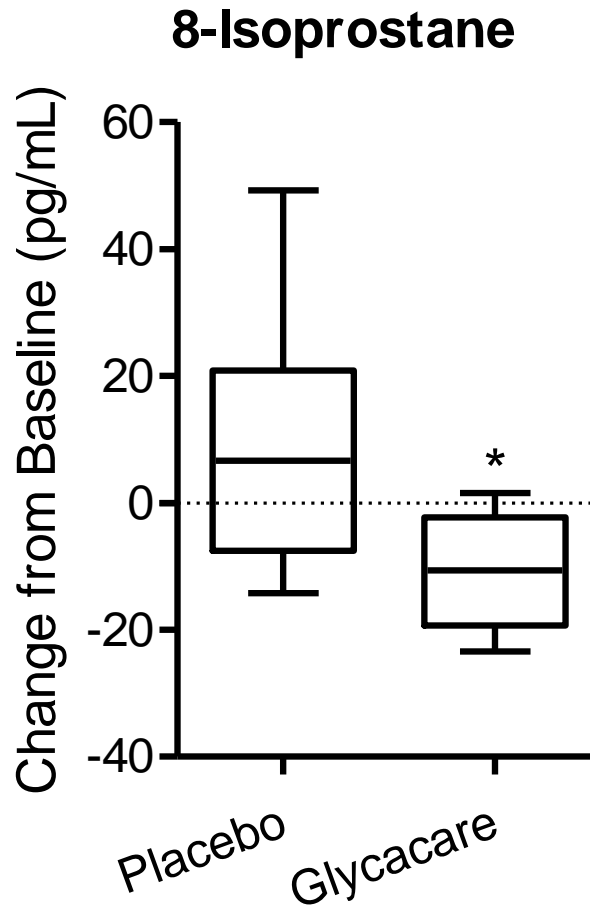
Oxidant Damage

- **Lipids:**
 - Peroxidation
- **Proteins:**
 - Denaturation and crosslinking
- **DNA:**
 - strand-breaks, base degradation
- **Genes activation:**
 - *c-fos*, *c-jun*, NF- κ B

Isoprostane-ELISA



Marker of Oxidative Stress



Conclusion

- Short-term intervention with GlyacaCare....
 - Did not affect body weight, serum insulin, serum glucose or hemoglobin A1C
 - Showed a tendency to decrease HOMA-IR index, improve glucose disposal
 - Reduced oxidative stress
- Further studies with a larger n, focussed on insulin-resistant subjects would help ascertain the utility of this formulation

Acknowledgment

- INBRE for the support
- Sabinsa Corporation
- Dr. Derek Smith (DEXA)
- Dr Timothy Robinson (Boot Strap)
- Drs. Yinan Hua and Sree Nair