

# **Diabetes News & Views**

A bi-monthly Scientific DDF Bulletin carrying news and views related to diabetes



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# Chief Patron

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Dia - Do, bet - your bit, es - ease: Do your bit to make life easy

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## Nutritional supplements in Diabetes mellitus

- Dr. Anupam Prakash

Use of nutritional supplements (NS) is in vogue since time immemorial. The more chronic a disease, and the more cumbersome the treatment regime, more is the tendency in the patient to avoid a life-long medication and resorting to alternative remedies. Nutritional supplements are one such remedy and come in the domain of complementary and alternative medicine (CAM) [1]. Diabetes is a chronic disease and its microvascular complications (neuropathy, nephropathy and retinopathy) as well as its macrovascular complications (stroke, heart disease, peripheral vascular disease) can be disabling and at times, devastating. The need to take a number of tablets twice or thrice a day and the that they are required life-long; and frightened by the fact that the medicines will eventually give way to injections of insulin; are sufficient reasons for patients to try nutritional supplements, even if they are ineffective and/or costlier; and worse still, occasionally damaging to the patient's health.

Nutritional supplement is defined as a product taken by mouth that contains dietary-ingredient, which can be a vitamin, mineral, herb, amino acid, enzyme or metabolite. Nutritional supplements are being offered to people to prevent development of diabetes and to patients with diabetes to supplement or avoid medications. The use of nutritional supplement has increased over the years. Many people, intentionally or unintentionally, hide the use of the nutritional supplements from their treating doctors. On the contrary, some practitioners prefer to prescribe nutritional supplements to their patients. In the era of evidence-based medicine, it would be prudent to mention that a number of small studies may show some or major benefits with the individual use of nutritional supplements, but several reviews and analysis have consistently failed to demonstrate any benefits with the use of nutritional supplements. At times, harm has been reported because of unsolicited effects on vital organs viz. the kidneys.

The marketing of nutritional supplements has received a great impetus with the availability of internet and its use for advertising and facility for online purchase of these agents [2]. A recent study [2] reported the inadequate information which is provided on internet, though the facility for purchase and delivery is very much facilitated. Only 40% website analysed clearly declared that the nutritional supplements offered were not a substitute for the diabetes medications that the patient is consuming. The abstract of this article is mentioned in this issue for reference of readers.

Diabetes mellitus is considered to be a state of oxidative stress, and this oxidative stress is considered to be contributory to the development of complications. However, use of antioxidant medications has not been consistently been proven to be of benefit. A recent review [3] (abstract mentioned in this issue) mentions that the use of antioxidants still remains a controversy.

The use of nutritional supplements including antioxidants, minerals, vitamins, omega-3 fatty acids, magnesium and chromium supplements, alpha-lipoic acid and herbal supplements still remains a matter of hot debate and present day scientific evidence is not robust to suggest their role in management of type 2 diabetes. However, this issue carries a number of abstracts of studies published in the last 6 months for the benefit of the readers. Despite being a matter of intense research, a definitive role is yet to be assigned to the use of nutritional supplements in the treatment algorithm of diabetes management.

#### References

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- Zatalia SR, Sanusi H. The role of antioxidants in the pathophysiology, complications and management of diabetes mellitus. Acta Medica Indonesiana 2013;45:141-7.

# Nutritional supplements for diabetes sold on the internet: business or health promotion?

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JBMC Public Health 2013, 13:777 doi:10.1186/1471-2458-13-777

#### Abstract

Background: Diabetes is one of the most widespread chronic disease. Although many medications are available for the treatment and prevention of diabetes, many people turn to nutritional supplements (Nss). In these years, the online sales have contributed to the growth of use of nutritional supplement. The aim of the research was to investigate the type of information provided by sales websites on nutritional supplements (Nss), and analyse the existence of scientific evidence about some of the most common ingredients found in available NSs for diabetes.

Methods: A web search was conducted in April 2012 to identify web sites selling NSs in the treatment of diabetes using Google, Yahoo and Bing! and the key word used was "Diabetes Nutritional Supplements". Website content was evaluated for the quality of information available to consumers and for the presence of a complete list of ingredients in the first NS suggested by the site. Subsequently, in order to analyze the scientific evidence on the efficacy of these supplements a PubMed search was carried out on the ingredients that were shared in at least 3 nutritional supplements.

Results: A total of 10 websites selling NSs were selected. Only half of the websites had a Food and Drug Administration disclaimer and 40% declared clearly that the NS offered was not a substitute for proper medication. A total of 10 NS ingredients were searched for on PubMed. Systematic reviews, meta-analyses or randomized controlled trial were present for all the ingredients except one. Most of the studies, however, were of poor quality and/or the results were conflicting.

Conclusions: Easy internet access to NSs lacking in adequate medical information and strong scientific evidence is a matter of public health concern, mainly considering that a misleading information could lead to an improper prevention both in healthy people and people suffering from diabetes. There is a clear need for more trials to assess the efficacy and safety of these NSs, better quality control of websites, more informed physicians and greater public awareness of these widely used products.

## Diabetes, obesity and gut microbiota.

Everard A, Cani PD.

Best Pract Res Clin Gastroenterol, 2013;27:73-83.

#### Abstract

The gut microbiota composition has been associated with several hallmarks of metabolic syndrome (e.g., obesity, type 2 diabetes, cardiovascular diseases, and non-alcoholic steatohepatitis). Growing evidence suggests that gut microbes contribute to the onset of the low-grade inflammation characterising these metabolic disorders via mechanisms associated with gut barrier dysfunctions. Recently, enteroendocrine cells and the endocannabinoid system have been shown to control gut permeability and metabolic endotoxaemia. Moreover, targeted nutritional interventions using non-digestible carbohydrates with prebiotic properties have shown promising results in pre-clinical studies in this context, although human intervention studies warrant further investigations. Thus, in this review, we discuss putative mechanisms linking gut microbiota and type 2 diabetes. These data underline the advantage of investigating and changing the gut microbiota as a therapeutic target in the context of obesity and type 2 diabetes.

## The Role of Antioxidants in the Pathophysiology, Complications, and Management of Diabetes Mellitus.

St. Rabiul Zatalia, Harsinen Sanusi

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Diabetes mellitus (DM) is a metabolic disorder that remains a major health problem in the world. It is characterized by relative or absolute deficiency of insulin secretion and/or insulin resistance that causes chronic hyperglycemia and impaired carbohydrates, lipids, and proteins metabolism. Diabetes has been known as an oxidative stress disorder caused by imbalance between free radical formation and the ability of the body's natural antioxidants. Many studies have suggested that oxidative stress play a role in systemic inflammation, endothelial dysfunction, impaired secretion of pancreatic  $\beta$  cells and impaired glucose utilization in peripheral tissues. In patients with type 2 diabetes mellitus (T2DM) who are at risk, intensive intervention with multiple drug combinations and lifestyle modifications showed a beneficial effect on vascular complications and reduce mortality rate due to cardiovascular disease and other causes. There has also been shown that neutralization of reactive molecules can significantly inhibit the development of endothelial dysfunction, cardiomyopathy, retinopathy, nephropathy, and neuropathy in patients with DM.

Recently the use of antioxidants still remains a controversy, but its use as a therapy for DM can be considered because its demonstrated effectiveness in lowering the risk of developing diabetes and its complications. Various antioxidants have been developed for oxidative stress treatment in DM, including the use of vitamins and supplements as well as the use of some components of plants and fresh fruits which have demonstrated antioxidant effect in DM patients. In some recent studies, some drugs routinely used in the treatment of DM also demonstrated antioxidant effects.

Key words: diabetes mellitus, type 2 diabetes mellitus, antioxidant.

### Nutrition supplementation for diabetic wound healing: a systematic review of current literature.

Maier HM, Ilich JZ, Kim JS, Spicer MT.

Skinmed. 2013 Jul-Aug; 11(4): 217-24; quiz 224-5.

There are 25.8 million people with diabetes in the United States (Centers for Disease Control and Prevention 2011 National Diabetes Fact Sheet). This number is expected to increase by 1 million per year. Diabetic foot ulcers (DFUs) occur in patients with a history of poorly controlled blood glucose. Almost 30% of people with diabetes aged 40 years or older experience DFUs caused by an impaired nerve sensation. It is one of the more persistent types of chronic wounds, which poses an economic burden on individuals and society and reduces the quality of life of patients and their families. This paper reviews the efficacy of nutrition supplementation in diabetic wound healing, including both human and animal studies. Using Preferred Reporting Items for Systematic Reviews and Meta-Analyses methods, the search was conducted in PubMed and ISI's Web of Science databases. Studies in which diabetic wounds/foot ulcers were treated with specific nutritional or herbal suplements were selected. This review includes 4 human and 9 animal studies that met the criteria of the search. Positive outcomes in the human studies were not significant while the nutritional supplements used in the animal studies were effective and promoted wound healing. The most notable effect of supplementation with curcumin, L-Arginine, or vitamin E have been shown in animal sudies. More human studies need to be conducted to determine the efficacy of these nutritional supplements in promoting wound healing.

## Nutritional requirements in pregnancy and use of dietary supplements.

Williamson C, Wyness L.

Community Pract. 2013 Aug; 86(8):44-7.

A new British Nutrition Foundation (BNF) Task Force report has been published, which looks in detail at the impact of early life nutrition on health and the risk of diseases in later life, including obesity, diabetes, cardiovascular disease, cancer, bone health, allergic disease and cognitive function. One of the aspects that the report covers in detail is the health and nutrition of pregnant women and where improvements in the maternal diet could be made. This article focuses on the report's findings with regard to the essential nutrients folic acid and vitamin D, including current intakes and status, uptake of supplements and v

#### Improved Meta-Analytic Methods Show No Effect of Chromium Supplements on Fasting Glucose.

Bailey CH.

Biol Trace Elem Res. 2013 Nov 30.

The trace mineral chromium has been extensively researched over the years in its role in glucose metabolism. Dietary supplement companies have attempted to make claims that chromium may be able to treat or prevent diabetes. Previous meta-analyses/systematic reviews have indicated that chromium supplementation results in a significant lowering of fasting glucose in diabetics but not in nondiabetics. A meta-analysis was conducted using an alternative measure of effect size, d ppc2 in order to account for changes in the control group as well as the chromium group. The literature search included MEDLINE, the Cochrane Controlled Trials Register, and previously published article reviews, systematic reviews, and meta-analyses. Included studies were randomized, placebo-controlled trials in the English language with subjects that were nonpregnant adults, both with and without diabetes. Sixteen studies with 809 participants (440 diabetics and 369 nondiabetics) were included in the analysis. Screening for publication bias indicated symmetry of the data. Tests of heterogeneity indicated the use of a fixed-effect model (I (2) = 0%). The analysis indicated that there was no significant effect of chromium supplementation in diabetics or nondiabetics, with a weighted average effect size of 0.02 (SE = 0.07), p = 0.787, CI 95% = -0.12 to 0.16. Chromium supplementation appears to provide no benefits to populations where chromium deficiency is unlikely, human studies need to be conducted to determine the efficacy of these nutritional supplements in promoting wound healing.

#### Interference of selenium and selenoproteins with the insulin-regulated carbohydrate and lipid metabolism.

Steinbrenner H.

Free Radic Biol Med. 2013 Dec:65:1538-47.

An assumed link between supranutritional intake of the micronutrient selenium (Se) and type 2 diabetes mellitus is discussed controversially. Se concentrations in the habitual diet and in dietary supplements are probably not sufficient to induce overt diabetes in healthy individuals. On the other hand, high plasma Se and selenoprotein P (Sepp1) levels have been found to be associated with biomarkers of an impaired carbohydrate and lipid homeostasis in humans. Moreover, abundant expression of antioxidant selenoproteins due to dietary Se oversupply resulted in hyperinsulinemia and decreased insulin sensitivity in animal models. This review discusses findings from animal and cell culture studies in search of molecular mechanisms underlying an interference of Se and selenproteins such as the Se transport and supply protein Sepp1 and the hydrogen peroxide-reducing selenoenzyme glutathione peroxidase 1 (GPx1) with insulin-controlled metabolic pathways. A probable rationale derives from the positive and negative regulation of both glucose-induced insulin secretion and insulin-induced signaling by hydrogen peroxide. Se status and GPx1 expression have been reported to affect the activity of insulin-antagonistic phosphatases that are regulated by hydrogen peroxide-mediated reversible oxidation of catalytic cysteine residues. Gpx1 and/or Sepp1 inhibited phosphorylation (activation) of key mediators in energy metabolism such as protein kinase B (Akt) and AMP-activated protein kinase (AMPK) in liver and/or skeletal muscle. Conversely, a dys-regulated carbohydrate metabolism in diabetes might affect plasma Se and Sepp1 levels, as the hepatic biosynthesis of Sepp1 is suppressed by insulin and stimulated under hyperglycemic conditions.

### Subgroup analysis for the risk of cardiovascular disease with calcium supplements.

Radford LT, Bolland MJ, Gamble GD, Grey A, Reid IR.

Bonekey Rep. 2013 Mar 6;2:293.

Calcium supplements have been reported to increase the risk of myocardial infarction (MI). We wished to determine whether the effects of calcium supplements on cardiovascular risk vary across different population groups. We modeled the effect of calcium (with or without vitamin D) on the time to incident cardiovascular events in pre-specified subgroups based on age, dietary calcium intake, body mass index, smoking history, history of hypertension, diabetes and prevalent cardiovascular disease, using interaction terms in Cox proportional hazards models in two randomized controlled trial data sets-our re-analysis of the Women's Health Initiative Calcium and Vitamin D study (WHI CaD), and ourpooled patient-level meta-analysis of trials of calcium supplements with or without vitamin D. For women in WHI CaD not taking calcium supplements at randomization (n=16 718), we found no significant interactions between treatment allocation, the risk of MI, stroke or coronary revascularization, or any of the baseline variables. In the pooled patient-level data set of six trials of calcium with or without vitamin D (n=24 869), there were also no significant interactions between treatment allocation, risk of MI or stroke, and any of the baseline variables. We found no evidence that the increased cardiovascular risk from calcium supplements differs across varying patient subpopulations. These findings suggest that targeted prescription of calcium supplements to specific population subgroups, such as younger people and those with low dietary calcium intake, should not be endorsed.

Concurrent physical activity modifies the association between n3 long-chain fatty acids and cardiometabolic risk in midlife adults.

Muldoon MF, Erickson KI, Goodpaster BH, Jakicic JM, Conklin SM, Sekikawa A, Yao JK, Manuck SB.

J Nutr. 2013 Sep; 143(9):1414-20.

Greater consumption of n3 ( $\omega$ 3) polyunsaturated fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) can reduce risk for cardiovascular disease events, yet their effects on metabolic risk factors and diabetes remain unclear. This cross-sectional study used a community volunteer sample to test whether the associations between n3 fatty acids and cardiometabolic risk vary as a function of physical activity. Participants were 344 generally healthy adults, 30-54 y of age, not taking fish oil supplements or confounding medications. Serum phospholipid EPA and DHA were used together (EPA+DHA) as a biomarker of n3 fatty acid exposure. Cardiometabolic risk was calculated as a continuous measure based on standardized distributions of blood pressure, waist circumference, HDL cholesterol, triglycerides, glucose, and a simple count of risk factors. Insulin resistance was estimated from the homeostatic model assessment. Physical activity was found to predict cardiometabolic risk (P < 0.02) and insulin resistance (P < 0.02) and to moderate the association between EPA+DHA and both cardiometabolic risk (P-interaction < 0.02) and insulin resistance (P-interaction < 0.02). Specifically, higher EPA+DHA was associated with lower cardiometabolic risk and insulin resistance in persons engaged in regular physical activity but not in relatively inactive individuals. These findings were noted in several components of cardiometabolic risk, in men and women separately, and in models adjusted for overall diet quality. In midlife adults, habitual physical activity may be necessary to unmask the salutary effects of n3 fatty acids on cardiometabolic risk and insulin resistance.

Oral administration of corn zein hydrolysate stimulates GLP-1 and GIP secretion and improves glucose tolerance in male normal rats and Goto-Kakizaki rats.

Higuchi N, Hira T, Yamada N, Hara H. Endocrinology. 2013 Sep;154(9):3089-98.

We have previously demonstrated that ileal administration of the dietary protein hydrolysate prepared from corn zein (ZeinH) stimulated glucagon-like peptide-1 (GLP-1) secretion and attenuated hyperglycemia in rats. In this study, to examine whether oral administration of ZeinH improves glucose tolerance by stimulating GLP-1 and glucose-dependent insulinotropic polypeptide (GIP) secretion, glucose tolerance tests were performed in normal Sprague-Dawley male rats and diabetic Goto-Kakizaki (GK) male rats. The test solution was gavaged before ip glucose injection in normal rats or gavaged together with glucose in GK rats. Blood samples were collected from the tail vein or by using the jugular catheter to measure glucose, insulin, GLP-1, and GIP levels. In the ip glucose tolerance test, oral administration of ZeinH (2 g/kg) significantly suppressed the glycemic response accompanied by an immediate normal rats. In contrast, oral administration of another dietary peptide, meat hydrolysate, did not elicit a similar effect. The glucose-lowering effect of ZeinH was attenuated by a GLP-1 receptor antagonist or by a GIP receptor antagonist. Furthermore, oral ZeinH induced GLP-1 secretion and reduced glycemic response in GK rats under the oral glucose tolerance test. These results indicate that the oral administration of the dietary peptide ZeinH improves glucose tolerance in normal and diabetic rats by its incretin-releasing activity, namely, the incretinotropic effect.

Daily flaxseed consumption improves glycemic control in obese men and women with pre-diabetes: a randomized study.

Bhutchins AM, Brown BD, Cunnane SC, Domitrovich SG, Adams ER, Bobowiec CE. Nutr Res. 2013 May; 33(5):367-75.

The study hypothesis was that fasting glucose, insulin, fructosamine, C-reactive protein, and interleukin-6 decrease and adiponectin increases with daily flaxseed consumption in overweight or obese individuals with pre-diabetes. In this randomized, cross-over study overweight or obese men and postmenopausal women (n=25) with pre-diabetes consumed 0, 13, or 26 g ground flaxseed for 12 weeks. Glucose, insulin, homeostatic model assessment (HOMA-IR), and normalized percent of  $\alpha$ -linolenic fatty acid (ALA) were significantly different by treatment (multiple analysis of variance, P=.036, P=.013, P=.008, P=.024 respectively). Paired t tests showed glucose decreased on the 13 g intervention compared to the 0 g period [13 g = -2.10  $\pm$  1.66 mg/L (mean  $\pm$  SEM), 0 g =  $9.22 \pm 4.44$  mg/L, P=.036]. Insulin decreased on the 13 g intervention but not the 26 g (P=.021) and 0 g (P=.013) periods (13 g =  $-2.12 \pm 1.00$  mU/L, 26 g =  $0.67 \pm 0.84$  mU/L, 0 g =  $1.20 \pm 1.16$  mU/L). HOMA-IR decreased on the 13 g period but not on the 26 g (P=.012) and 0 g (P=.008) periods (13 g =  $-0.71 \pm 0.31$ , 26 g =  $0.27 \pm 0.24$ , 0 g =  $0.51 \pm 0.35$ ). The a-linolenic fatty acid decrease for the 0 g period was different than the 13 g (P=.024) and 26 g (P=.000) periods (13 g =  $0.20 \pm 0.04$ , 26 g =  $0.35 \pm 0.07$ , 0 differences. Flaxseed intake decreased glucose and insulin and improved insulin sensitivity as part of a habitual diet in overweight probase individuals with pre-diabetes

## Zinc as a potential coadjuvant in therapy for type 2 diabetes.

Ruz M, Carrasco F, Rojas P, Codoceo J, Inostroza J, Basfi-fer K, Valencia A, Vásquez K, Galgani J, Pérez A, López G, Arredondo M, Perez-Bravo F.

Food Nutr Bull. 2013 Jun; 34(2):215-21.

**Background**: Type 2 diabetes is highly prevalent in populations having high rates of overweight and obesity. It is a chronic condition responsible for long-term severe dysfunction of several organs, including the kidneys, heart, blood vessels, and eyes. Although there are a number of pharmacologic products in the market to treat insulin resistance and impaired insulin secretion—the most prominent features of this disease—interventions directed at preserving the integrity and function of beta-cells in the long term are less available. The use of some nutrients with important cellular protective roles that may lead to a preservation of beta-cells has not been fully tested; among these, zinc may be an interesting candidate.

Objective: To assess the potential of zinc supplementation as coadjuvant to diabetes therapy.

Methods: This article reviews the available information on the use of zinc as part of diabetes therapy.

Results: Cellular and animal models provide information on the insulin mimetic action of zinc, as well as its role as a regulator of oxidative stress, inflammation, apoptosis, and insulin secretion. Zinc supplementation studies in humans are limited, although some positive effects have been reported; mainly, a modest but significant reduction in fasting glucose and a trend to decreased glycated hemoglobin (HbA1c).

**Conclusions:** Zinc supplementation may have beneficial effects on glycemic control. Nevertheless, among the studies considered, the vast majority lasted for 6 months or less, suggesting the importance of conducting long-duration studies given the characteristics of type 2 diabetes as a chronic disease.

# A randomized clinical trial with two doses of an enteral diabetes-specific suplements in elderly patients with diabetes mellitus type 2.

de Luis DA, Izaola O, de la Fuente B, Terroba MC, Cuellar L, Cabezas G.

Eur Rev Med Pharmacol Sci. 2013 Jun;17(12):1626-30.

**Objectives:** The aim of our study was to investigate whether two different daily doses of a high monounsaturated fatty acid (MUFA) specific diabetes enteral formula could improve nutritional variables as well as metabolic parameters.

Patients And Methods: We conducted a randomized, open-label, multicenter, parallel group study. 27 patients with diabetes mellitus type 2 with recent weight loss were randomized to one of two study groups: group 1 (two cans per day) and group 2 (three cans per day) for a ten week period.

Results: A significative decrease of HbA1c was detected in both groups. The decrease 0.98% (confidence interval 95% 0.19-1.88) was higher in group 2 than group 1 0.60% (confidence interval 95% 0.14-1.04). A significant increase of weight, body mass index, fat mass, albumin, prealbumin and transferrin was observed in both groups without statistical differences in this improvement between both groups. The increase of weight 4.59kg (confidence interval 95% 1.71-9.49) was higher in group 2 than group 1 1.46% (confidence interval 95% 0.39-2.54). Gastrointestinal tolerance (diarrhea episodes) with both formulas was good, without statistical differences (7.60% vs 7.14%; ns).

**Conclusions:** A high monounsaturated fatty acid diabetes-specific supplement improved HbA1c and nutritional status. These improvements were higher with three supplements than with two per day.

Resveratrol supplementation improves white adipose tissue function in a depot-specific manner in Zucker diabetic fatty rats.

Beaudoin MS, Snook LA, Arkell AM, Simpson JA, Holloway GP, Wright DC.

Am J Physiol Regul Integr Comp Physiol. 2013 Sep;305(5):R542-51.

Resveratrol (RSV) is a polyphenolic compound suggested to have anti-diabetic properties. Surprisingly, little is known regarding the effects of RSV supplementation on adipose tissue (AT) metabolism in vivo. The purpose of this study was to assess the effects of RSV on mitochondrial content and respiration, glyceroneogenesis (GNG), and adiponectin secretion in adipose tissue from Zucker wt) for 6 wk. Changes in adipose tissue metabolism were assessed in subcutaneous (scAT) and intra-abdominal [retroperitoneal (rpWAT), epididymal (eWAT)] adipose tissue depots. ZDF RSV rats showed lower fasting glucose and higher circulating adiponectin, as well as lower glucose area under the curve during intraperitoneal glucose and insulin tolerance tests than ZDF with increases in adipose tissue triglycerides and adiponectin secretion were higher in scAT from ZDF RSV rats, concurrent dehydrogenase-E1a (PDH) (Ser293) protein content in this depot. Moreover, uncoupled mitochondrial respiration and complex I subunit IV (COX4) protein content. In vitro treatment of scAT and rpWAT, which correlated with increases in cytochrome c oxidase (PDK4) and peroxisome proliferator-activated receptor (PPAR)-y coactivator-1a (PGC-1a) mRNA expression. Collectively, these exerction.

PMID: 23824959 [PubMed-indexed for MEDLINE]

Effects of probiotics in patients with diabetes mellitus type 2: study protocol for a randomized, double-blind, placebo-controlled trial.

Alokail MS, Sabico S, Al-Saleh Y, Al-Daghri NM, Alkharfy KM, Vanhoutte PM, McTernan Pg

Trials. 2013 Jul 4;14:195.

Background: Low grade chronic inflammation is observed in patients with type 2 diabetes mellitus (T2DM). Endotoxin derived from gut bacteria may act as a potent inflammatory stimulant. Probiotics, which are believed to contain healthpromoting live microorganisms, may influence circulating endotoxin levels. Ingestion of live probiotic cultures may alter gut microbiota in a the aim of this study is to characterize the beneficial effects of probiotics on circulating endotoxin levels and other biomarkers related to systemic low-grade inflammation in patients with T2DM.

Methods: One hundred and twenty consenting adult Saudi T2DM patients (naïve or newly diagnosed and without co-morbidities) will be enrolled in this clinical trial and randomized to receive daily placebo or probiotics (Ecologic®Barrier) for 26 weeks in a double-blind manner. Inflammatory and metabolic markers will be measured and fecal samples analyzed. Measurements/samples will be obtained at baseline and after 4, 8, 12/13 and 26 weeks of treatment.

Discussion: It is expected that the probiotic product will induce beneficial changes in gut microbiota, reduce the systemic inflammatory state through altering systemic endotoxin levels and, as such, reduce the systemic inflammatory response observed in T2DM subjects.

Irial Registration: ClinicalTrials.gov Identifier: NCT01765517.



## **Delhi Diabetic Forum**

organises
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Registration form available on the website http://delhidiabeticforum.org/RegistrationForm.pdf

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