بسم الله الرحمن الرحيم

MONA MAGHRABY

شبكة المعلومات الجامعية

التوثيق الالكتروني والميكروفيلم

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جامعة عين شمس

التوثيق الإلكتروني والميكروفيلم

قسم

نقسم بالله العظيم أن المادة التي تم توثيقها وتسجيلها
علي هذه الأقراص المدمجة قد أعدت دون أية تغيرات

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تحفظ هذه الأقراص المدمجة بعيدا عن الغبار

MONA MAGHRABY

The effect of *Nigella sativa* oil versus metformin on the biochemical parameters and clinical outcome of newly diagnosed type 2 diabetes mellitus patients

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List of contents

AGI	α-glucosidase inhibitors
ASA	Acetylsalicylic acid
ACC	Acteyl-CoA carboxylase
AMP	Adenosine monophosphate
AMPK	Adenosine monophosphate-activated protein kinase
ATP	Adenosine triphosphate
K_{ATP}	Adenosine triphosphate dependent potassium channels
AGEs	Advanced glycation end-products
ALT	Alanine aminotransferase
ADA	American Diabetes Association
ACEI	Angiotensin-converting-enzyme inhibitors
ARBs	Angiotensin II receptor blockers
AST	Aspartate aminotransferase
ASCVD	Atherosclerotic cardiovascular disease
%B	β-cell function
BMI	Body mass index
CVD	Cardiovascular disease
CAT	Catalase
CKD	Chronic kidney disease
CAM	Complementary and alternative medicine
CHF	Congestive heart failure
CGM	Continuous glucose monitoring
CSII	Continuous subcutaneous insulin infusion
CAD	Coronary artery diseases
COX-2	Cyclooxygenase-2
CFRD	Cystic fibrosis–related diabetes
DM	Diabetes mellitus
DKA	Diabetic ketoacidosis
DPN	Diabetic peripheral neuropathy
DASH	Dietary Approaches to Stop Hypertension
DPP-4	Dipeptidyl peptidase-4

eGFR	Estimated glomerular filtration rate
ECFV	Extracellular fluid volume
FPG	Fasting plasma glucose
FDA	Food and Drug Administration
FFA	Free fatty acids
GERD	Gastroesophageal reflux disease
GIT	Gastrointestinal tract
GDM	Gestational diabetes mellitus
GFR	Glomerular filtration rate
GLP-1	Glucagon-like peptide-1
GIP	Glucose-dependent insulinotropic polypeptide
GLUT 4	Glucose transporter 4
GADAs	Glutamic acid decarboxylase autoantibodies
A1C	Glycated hemoglobin
GI	Glycemic index
GL	Glycemic load
HF	Heart failure
HFpEF	Heart failure with preserved ejection fraction
HFrEF	Heart failure with reduced ejection fraction
HGP	Hepatic glucose production
HCV	Hepatitis C virus
HDL	High-density lipoprotein
HOMA	Homeostatic model assessment
2h PP	2 hours post prandial
HLA	Human leukocyte antigen
HMG-CoA reductase	3-hydroxy-3-methylglutaryl coenzyme A reductase
HBOT	Hyperbaric oxygen therapy
HHS	Hyperosmolar hyperglycemic state
HTN	Hypertension
IFG	Impaired fasting glucose

IGT	Impaired glucose tolerance
IAAs	Insulin autoantibodies
IR	Insulin resistance
%S	Insulin sensitivity
IL	Interleukin
ICA	Islet cell antibody
LADA	Late-onset autoimmune diabetes in adults
LKB1	liver kinase B1
LOPS	Loss of protective sensation
LDL	Low-density lipoprotein
MACE	Major adverse cardiovascular events
MODY	Maturity-onset diabetes of the young
LD50	Median lethal dose
MNT	Medical nutrition therapy
NHPs	Natural health products
NPH	Neutral protamine Hagedorn
NODAT	New onset diabetes after transplantation
NS	*Nigella sativa*
NO	Nitric oxide
NF-kB	Nuclear factor kappa-light-chain-enhancer of activated B cells
OADs	Oral anti-diabetic drugs
OGTT	Oral glucose tolerance test
PAD	Peripheral arterial disease
PVD	Peripheral vascular disease
PPARγ	Peroxisome proliferator-activated receptor γ
PTEN	Phosphatase and tensin homolog
PI3K–Akt	Phosphatidylinositol 3-kinase and Protein Kinase B pathway
PCOS	Polycystic ovary syndrome
PCSK9	Proprotein convertase subtilisin/kexin type 9
RCTs	Randomized controlled trials
ROS	Reactive oxygen species

RBCs	Red blood cells
SMBG	Self-monitoring of blood glucose
Sr Cr	Serum creatinine
SGLT2	Sodium-glucose co-transporter 2
SPSS	Statistical Package for Social Sciences
SU	Sulfonylurea
SUR	Sulfonylurea receptor
SOD	Superoxide dismutase
TZD	Thiazolidinedione
TQ	Thymoquinine
TCM	Traditional Chinese medicine
TG	Triglycerides
TAC	Total antioxidant capacity
TC	Total cholesterol
TOS	Total oxidant status
TNF-α	Tumor necrosis factor
T1DM	Type 1 diabetes mellitus
T2DM	Type 2 diabetes mellitus
WC	Waist circumference
WHO	World Health Organization

List of Tables

List of Figures

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Abstract

Purpose Nature is a phenomenal treasure of remedies. Numerous previous studies reported that *Nigella sativa* (NS) improved glycemic control, reduced insulin resistance, and improved lipid profile. NS was never investigated before as a monotherapy for newly diagnosed type 2 diabetes mellitus (T2DM) patients. Our aim was to investigate the potential metabolic benefits of NS monotherapy in newly diagnosed T2DM patients.

Method Prospective, open-label randomized clinical trial at outpatient endocrinology clinic at Ain-Shams University hospital. Eligible patients were randomly assigned to either metformin tablets or NS oil capsules. Both groups received treatment for 3 months. Glycemic index (FBG, 2hpp, A1C, insulin sensitivity %S, secretory function %B, insulin resistance IR), lipid profile (TC, LDL, HDL, TG), liver and kidney functions (AST, ALT, Sr cr), total antioxidant capacity (TAC), weight, waist circumference (WC) and body mass index (BMI) were assessed at baseline and at the end of treatment period.

Results A concentration of 1350 mg/day NS oil in newly diagnosed T2DM patients was inferior to metformin in terms of lowering FBG, 2 h pp, and A1C or increasing %B. However, NS was comparable to metformin in lowering weight, WC, and BMI significantly. NS was comparable to metformin in regards of their effects on fasting insulin, %S, IR, ALT, TC, LDL, HDL, TG, and TAC. Metformin showed significant increase in AST and creatinine which were reserved in NS group.

Conclusion NS administration in newly diagnosed T2DM was tolerable with no side effects as compared to metformin; however, it was inferior to metformin in terms of diabetes management.

Keywords ●Newly diagnosed type 2 diabetes mellitus ● Nigella sativa ● Metformin