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A study investigating the effect over 12 weeks of the novel herbal composition SR2004 on haemoglobin A1c, fasting blood glucose and lipids in type 2 diabetic patients

Submission date
27/05/2017

Recruitment status
No longer recruiting

Registration date
12/06/2017

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Type 2 diabetes mellitus (T2DM) is a long term condition where a person is unable to control their blood sugar (glucose) levels as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). It is becoming increasingly common and represents a major global health concern. Conventional treatment for T2DM usually involves injecting insulin or taking pills to help control blood sugar levels, however these methods are not always effective. In this context there is renewed interest in evaluating the effects of traditional herbal therapies which have been used, in some cases, for millennia. The aim of this study is to look at the effects of a new herbal combination called SR2004 in patients with T2DM.

Who can participate?
Adults with T2DM

What does the study involve?
Participants in the study continue with their usual diets, exercise regimes and medicines. All participants are treated with SR2004. This is made up from mulberry, artemisia, nettle, cinnamon bark and dandelion. Patients are treated by mouth in the form of either a syrup or capsule three times a day for 12 weeks. At the start of the study and after 12 weeks of treatment, participants have blood samples collected to measure their blood sugar control and the level of fat in the blood. In addition, any side effects from the supplement are recorded.

What are the possible benefits and risks of participating?
Participants may benefit from a lowering of blood sugar and fats as well as benefiting from close monitoring of their diabetes. There are no notable risks involved with participating.

Where is the study run from?
D.S.Polyclinic (Isreal)

When is study starting and how long is it expected to run for?
February 2008 to February 2010

Who is funding the study?
Maccabi Healthcare Services (Isreal)

Who is the main contact?
Dr Dov Fogel
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
918

Study information

Scientific Title
Single arm, non-blinded study assessing the effect of the novel herbal composition SR2004 on the primary endpoint haemoglobin A1c and secondary endpoints fasting blood glucose, and lipid profile in type 2 diabetic patients recruited in Israel over a 12 week period

Study objectives
Does supplementation with the compound SR2004
1. Reduce blood haemoglobin A1c (HbA1c) by >1% after 12 weeks compared to Week 0?
2. Reduce fasting blood glucose by a significant level at 12 weeks compared to Week 0?

3. Reduce blood total cholesterol and triglycerides by a significant level at 12 weeks compared to Week 0?
4. Result in an acceptable side effect and safety profile?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Helsinki committee of Maccabi Health Services, 21/08/2008, ref: 20080395

Study design
Single-centre unblinded single arm interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
All patients included in the study continue their usual diets, exercise regimes and medical treatments. They will receive SR2004 at dose 300 millilitres three times daily taken 30 minutes before mealtimes (or a capsule form 500 milligram per capsule, dose two capsules three times daily, thirty minutes before meals). SR2004 supplements will be continued for 12 weeks, with weekly clinical reviews by the trial physician during this time. Patients are encouraged to attend a follow up visit at week 24 to reassess clinical and blood parameters off SR2004 supplementation.

Intervention Type
Supplement

Primary outcome(s)
Glycated hemoglobin (HbA1c) is measured using the glycated hemoglobin test on blood samples collected at baseline and 12 weeks.

Key secondary outcome(s))
1. Fasting blood glucose is assessed by laboratory blood glucose test at baseline nd thereafter weekly up to week 12
2. Blood total cholesterol and triglyceride levels are assessed by laboratory lipid profile blood test at pre-enrolment (week -2), 6 and 12 weeks
3. Safety and side effect information is assessed by patient interview (weekly from baseline to week 12), review of patient-recorded blood sugar measurements (weekly from baseline to week 12), clinical examination (at baseline, 6 and 12 weeks) and review of blood chemistry and blood counts (6 and 12 weeks)

Completion date
01/02/2010

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of T2DM and any combination of oral hypoglycemics and/or insulin
2. HbA1c 7.1–10% in the last 6 months
3. Body mass index (BMI) <45 kg/m2
4. Ability to provide written informed consent
5. No participation in an investigational drug study (or use of herbal supplementation) within the prior 30 days
6. Women of childbearing age are required to have a negative pregnancy test and use contraception for the duration of the trial
7. Aged 18 years and over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
119

Key exclusion criteria
1. Type 1 diabetes mellitus
2. Treatment with the drugs acarbose or rosiglitazone for more than 2 weeks in the last six months
3. Concomitant malignancy
4. Concomitant heart failure grade 2-4 (American Heart Association)
5. Liver dysfunction (alanine aminotransferase or aspartate aminotransferase more than 3 times upper limit of normal values) 6. Renal failure (serum creatinine more than 1.3 times upper limit normal for women and 1.4 for men)
7. History of severe psychiatric illness on medication

Date of first enrolment
01/09/2008

Date of final enrolment
01/12/2009

Locations

Countries of recruitment
Israel

Study participating centre
D.S.Polyclinic
22 Ben Gurion Street
Givat Shmuel
Tel Aviv
Israel
54017

Sponsor information

Organisation
Maccabi Healthcare Services

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Maccabi Healthcare Services

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Dov Fogel (foge.dov@gmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/04/2018	11/07/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes