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Effects of Hintonia latiflora in type 2 diabetics

Submission date	Recruitment status	[_] Prospectively registered
31/08/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/09/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/10/2014	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
We were carrying out a study to measure the effect of a dietary supplement containing an extract from the bark of the South American tree Hintonia latiflora on blood sugar control. The aim of the study was to see if preparations of this plant extract are useful in the treatment of local cases of diabetes.

Who can participate?
Adults suffering from age-related diabetes.

What does the study involve?
Participants will take one capsule before meals twice daily while adhering to the prescribed diet. Only routine examinations will be carried out during the study, such as measurement of blood sugar values and HbA1c as a parameter for long-term development of diabetes.

What are the possible benefits and risks of participating?
A delay of the requirement of treating diabetics with insulin is a clinical target in diabetes therapy, and increases the quality of life of patients. No adverse reactions have been observed in previous examinations and experience with exposure to Hintonia bark preparations. Participating patients are screened for potential adverse events.

Where is the study run from?
A medical diabetes center.

When is the study starting and how long is it expected to run for?
The study started in 2009 and was stopped in 2011.

Who is funding the study?
Gehrlicher Pharmazeutische Extrakte in Eurasburg/Obb., Germany.

Who is the main contact?
Dr Marta Korecova
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Gehrlicher 01/2007

Study information

Scientific Title
Six-month clinical trial to investigate the effect of Hintonia latiflora in the dietetic treatment of mild and moderate type 2 diabetes mellitus

Study objectives
Intake of capsules with an extract of the bark of the South American plant Hintonia latiflora as a dietary measure contributes to controlling and improving parameters of diabetes mellitus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Open prospective dietary intervention study with a duration of 6 months

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild and moderate diabetes mellitus of type II (age-related)

Interventions
Sucontral® D Capsules, Harras Pharma Curarina, Munich, with 100 mg of a dry concentrate per capsule (extraction solvent ethanol 32°%) from the bark of the Central American plant Hintonia latiflora (SESSÉ & MOC. ex DC.) BULLOCK (Rubiaceae). The plant material came from controlled collection. Per capsule, 24 mg polyphenols are supplied. The capsules also contained 30 mg vitamin C, 5 mg vitamin E, 0.7 mg vitamin B1, 0.8 mg vitamin B2, 1 mg vitamin B6, 0.5 µg vitamin B12, 100 µg folic acid, 75 µg biotin, 2.5 mg zinc and 25 µg chromium. 1 capsule before meals twice daily while adhering to the prescribed diet.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Fasting blood sugar and postprandial blood sugar (two hours after food intake) as well as blood pressure and body weight were recorded at monthly intervals. The HbA1c value was recorded after three and six months as were the liver values and blood lipids.

Key secondary outcome(s)
1. Safety laboratory including liver function tests
2. Physical symptoms
3. Adverse events

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Type 2 diabetics
2. Between the ages of 45 and 80
3. Neither oral antidiabetic agents nor insulin were used
4. Prescribed diet had led to stable but not nearly normoglycaemic values

As a condition for inclusion in the study, diabetic symptoms must have existed for a period of at least 12 months. The values for fasting blood sugar had to be in the range from 7-14 mmol/l (normal value: 3.9-5.4 mmol/l).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Key exclusion criteria
To be excluded were patients for whom there was a doubt about the reliability with respect to the adherence to the dietetic guidelines (e.g., with regard to alcohol consumption). Other exclusion reasons were severe diabetic symptoms, progressive life-threatening diseases, hepatic dysfunction or renal insufficiency (deviations of GOT, γGT and AP of more than twice the normal value, serum creatinine > 130 µmol/l), hypoglycaemic crises not noticed in time, retinopathy, pregnancy, malignant tumours and/or drug or alcohol dependence in the medical history.

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Slovakia

Study participating centre
Head of Diabetes Department
Trencin
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91101

Sponsor information

Organisation
Gehrlicher Pharmazeutische Extrakte GmbH (Germany)

ROR
https://ror.org/04qx49k93

Funder(s)

Funder type
Industry

Funder Name
Gehrlicher Extrakte (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/03/2014		Yes	No