Metabolic effects of Diabecinn (oral cinnamon extract) in diabetes type 2, a placebo-controlled randomized clinical trial.

No registrations found.

Ethical review Positive opinion **Status** Suspended

Health condition type -

Study type Interventional

Summary

ID

NL-OMON28157

Source

Nationaal Trial Register

Brief title

Diabecinn trial

Health condition

Type 2 diabetes

Sponsors and support

Primary sponsor: OTC Pharma

Intervention

Outcome measures

Primary outcome

HbA1c.

Secondary outcome

- 1. Lipid profile;
- 2. 6 point glucose profile;
- 3. Hypoglycemia;
- 4. Body weight;
- 5. Free fatty acids;
- 6. CRP.

Study description

Background summary

Diabetes is a disease characterized by abnormalities in both lipid and glucose metabolism. In a placebo controlled study reported by Khan, 15 to 25% reductions in fasting glucose, total and LDL cholesterol and triglycerides were seen after 40 days of treatment. While these results are very promising, a trial with longer duration and a widely accepted measure of overall glucose homeostasis, i.e. HbA1c, is needed.

Study objective

The main objective of this randomized, placebo-controlled trial is to determine the effects of cinnamon extract on HbA1c and lipid profiles in type 2 diabetic patients.

Study design

N/A

Intervention

Diabecinn tid or placebo.

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

- 1. Type 2 diabetes patients;
- 2. Age 35-70 years inclusive;
- 3. HbA1c between 7 and 12% inclusive.

Exclusion criteria

- 1. Pregnancy;
- 2. Breast-feeding.

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

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Masking: Double blinded (masking used)

Control: Placebo

Recruitment

NL

Recruitment status: Suspended Start date (anticipated): 01-05-2006

Enrollment: 120

Type: Anticipated

Ethics review

Positive opinion

Date: 21-03-2006

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

RegisterIDNTR-newNL579NTR-oldNTR635Other: N/A

ISRCTN ISRCTN36704940

Study results

Summary results

N/A