

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

NTR

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

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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

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

Register	ID
NTR-new	NL579
NTR-old	NTR635
Other	: N/A
ISRCTN	ISRCTN36704940

Study results

Summary results

N/A