ISRCTN36704940 https://doi.org/10.1186/ISRCTN36704940

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

Submission date	Recruitment status	[X] Prospectively registered
28/04/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/04/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/04/2006	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J.H. DeVries

Contact details
Academic Medical Center
Department of Internal Medicine, F4-222
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 5669111
j.h.devries@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym
Diabecinn trial

Study objectives
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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Diabetes Mellitus type 2 (DM type II)

Interventions
Diabecinn three times a day (tid) or placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Diabecinn

Primary outcome measure
HbA1c.

Secondary outcome measures
1. Lipid profile
2. 6 point glucose profile
3. Hypoglycemia
4. Body weight
5. Free fatty acids
6. C-reactive protein (CRP)

Overall study start date
01/05/2006

Completion date
01/01/2007

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Pregnancy
2. Breast-feeding

Date of first enrolment
01/05/2006

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

Sponsor details
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
University/education

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
OTC Pharma

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration