

Improving clinical care of diabetes mellitus; randomized clinical trial

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23763

Source

NTR

Brief title

Met_AA trial

Health condition

Diabetes Mellitus

Sponsors and support

Primary sponsor: Government hospital
Community diabetes clinic

Source(s) of monetary or material Support: Self-financed research

Intervention

Outcome measures

Primary outcome

- improved glucose tolerance
- Reduction in lipid profiling

Secondary outcome

- a. Reduction in diabetes related complications over a period of 12 months
- b. Improved clinical outcomes in lipid profiling.
- c. comparison between Ascorbic acid Vs Acetylsalicylic acid combination with metformin.

Study description

Study objective

- a. Ascorbic acid in combination with metformin (500mg BD) improve the glucose tolerance with a daily dose of 500mg over a period of 12 months.
- b. Ascorbic acid with metformin reduce the adverse effects/events.
- c. Acetylsalicylic acid in combination with metformin (500mg BD) improve the glucose tolerance with a daily dose of 100mg over a period of 12 months.
- d. Acetylsalicylic acid with metformin reduce the adverse effects/events.

Study design

0 months

3 months

6 months

12 months

Intervention

- a. control arm - metformin (500mgBD) usual dose
- b. Group 1 - randomized - metformin (500mgBD) + Ascorbic acid (500mg OD) - for 12 months
- c. Group 2 - randomized - metformin (500mg BD) + Acetylsalicylic acid (100mg OD) for 12 months

Contacts

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Eligibility criteria

Inclusion criteria

- a. patient age more than 18years
- b. diagnose with diabetes mellitus type 2 not more than 5 years
- c. both male/female
- d. prescribed with metformin 500mg BD dosing
- e. glucose intolerance with last 3 reading of FBS or SBG
- f. HbA1c more than 7% with minimum last 6 months
- g. only diagnosed with diabetes mellitus type 2.

Exclusion criteria

- a. patient with age less than 18 years

- b. diabetes history of more than 5 years
- c. transexual
- d. metformin dose more than 1 g/day or in-combination
- e. HbA1c less than 7% with last two readings
- f. patients with another systemic complications except diabetes mellitus type 2.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Other
Start date (anticipated):	01-11-2015
Enrollment:	300
Type:	Unknown

Ethics review

Positive opinion	
Date:	20-10-2016
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	NL5920
NTR-old	NTR6100
Other	10-776-6941 : NMRR

Study results

Summary results

In Process - Featuring Diabetic Care with Ascorbic Acid & Acetylsalicylic Acid; A Randomized Single Blind Control Trial