

AFFIRM trial:Alterations in Faecal Flora Intrinsically Related to Metformin.

No registrations found.

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

Summary

ID

NL-OMON21550

Source

Nationaal Trial Register

Brief title

AFFIRM trial

Health condition

Type 2 diabetes, metformin, gutmicrobiota

Sponsors and support

Primary sponsor: Academic Medical Centre

PO Box 22660

1100 DD Amsterdam

Netherlands

Source(s) of monetary or material Support: Academic Medical Centre

PO Box 22660

1100 DD Amsterdam

Netherlands

Intervention

Outcome measures

Primary outcome

Changes in faecal flora after 15 weeks.

Secondary outcome

1. Glycemic control;
2. Biochemical parameters;
3. Inflammatory parameters;
4. Weight.

Study description

Background summary

Metformin is the first line treatment in newly diagnosed patients with diabetes type 2. Metformin is an effective anti-hyperglycemic agent, although its precise mechanism of action is still unknown. In our study we will try to confirm the hypothesis that the working mechanism of metformin can be partly explained by its effect on the gut microbiota by studying both bacterial changes and these pathways simultaneously. Thus, the improved insulin sensitivity with metformin use can probably be explained by the influence of metformin on the composition of the gut microbiota, with changes in incretin secretion and inflammation pathways as secondary effectors.

Study objective

Hypothesis: the working mechanisms of metformin can be partly explained by its effect on the composition of the gut microbiota, with changes in incretin secretion and inflammatory pathways as secondary effects.

Study design

1. Baseline;
2. 5wk;
3. 10wk;
4. 15wk.

Intervention

1. Arm 1- 15 weeks metformin;
2. Arm 2- 15 weeks insulin (lantus).

Contacts

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Eligibility criteria

Inclusion criteria

1. Male obese subjects with an impaired fasting glucose or newly diagnosed diabetes;
2. 21-65 yr;
3. BMI <45 kg/m².

Exclusion criteria

1. Renal failure;
2. Liver function problems;
3. (History of) alcoholism.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2009
Enrollment:	18
Type:	Anticipated

Ethics review

Positive opinion	
Date:	24-04-2009
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	NL1674
NTR-old	NTR1775
Other	CCMO : 26948
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A