LIMIT-1: Lowering the Incidence of vascular complications with Metformin in patients with Impaired glucose Tolerance and a recent transient ischaemic attack or minor ischaemic stroke: a phase II randomised, controlled trial

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Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Acronym

LIMIT-1

Study objectives

Metformin will be tolerated in patients with Transient Ischaemic Attack (TIA) or minor ischaemic stroke and will result in blood glucose lowering.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the Medical Ethics Committee of Erasmus Medical Centre on the 5th December 2006 (ref: NL15011.078.06 [local METC number MEC-2006-303]).

Study design

Randomised, open-label, multicentre, controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Transient ischaemic attack or minor ischaemic stroke

Interventions

Patients will be randomised for metformin or no oral anti-diabetic drug (open-label) on top of optimal standard treatment, including lifestyle advice aimed at weight reduction and regular physical exercise.

Patients allocated to metformin will be treated with metformin for three months from the day of randomisation until study end. They will start with a daily dose of 500 mg that will be slowly increased in one-month time to a daily dose of 2,000 mg in two gifts. All patients will be followed for three months.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Metformin

Primary outcome(s)

- 1. Tolerability of metformin treatment (measured as number of patients still on treatment after three months)
- 2. The safety of metformin treatment (which will be continuously monitored)
- 3. The adjusted difference in two-hour post-load glucose levels at three months

Primary outcomes will be measured at three months for feasability (safety will be continuously monitored). Primary outcome on effect on post-load glucose level will be measured at three months, expressed as a for baseline adjusted difference in mean two-hour post-load glucose levels at three months between treatment groups.

Key secondary outcome(s))

- 1. Differences in fasting glucose levels
- 2. Insulin resistance
- 3. Body mass index
- 4. Percentage of patients with a normal glucose tolerance at three months

Secondary outcomes will be measured at three months, as a for baseline adjusted difference between groups.

Completion date

01/02/2008

Eligibility

Key inclusion criteria

- 1. Men or women 18 years and over
- 2. TIA/minor ischaemic stroke (modified Rankin Score three or less) within six months
- 3. Impaired fasting glucose (fasting glucose level of 5.6 to 6.9 mmol/L) and/or impaired glucose tolerance (two-hour post-load glucose level of 7.8 to 11.0 mmol/L)
- 4. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Known or newly diagnosed diabetes mellitus
- 2. Contraindication for metformin:

- 2.1. Renal impairment (serum creatinine greater than 135 micromol/L for men, and greater than 110 micromol/L for women)
- 2.2. Hepatic disease (liver enzymes increased twice the upper limit of normal)
- 2.3. A past history of lactic acidosis
- 2.4. Cardiac failure requiring pharmacological therapy
- 2.5. Chronic hypoxic lung disease
- 2.6. Pregnancy
- 2.7. Breast feeding
- 3. Severe comorbidity interfering with follow-up

Date of first enrolment

01/02/2007

Date of final enrolment

01/02/2008

Locations

Countries of recruitment

Netherlands

Study participating centre Stroke Research Assistant

Rotterdam Netherlands 3000 DR

Sponsor information

Organisation

Erasmus Medical Centre (The Netherlands)

ROR

https://ror.org/018906e22

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Erasmus Medical Centre (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration