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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

Submission date 11/04/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 11/04/2007	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 20/03/2008	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/02/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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)

Sponsor details
Department of Neurology
P.O. Box 2040
Rotterdam
Netherlands
3000 CA

Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (The Netherlands)

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