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Metformin improves endothelial function, endothelial progenitor cells and cardiovascular risk factors in type 1 diabetes

Submission date
16/05/2012

Recruitment status
No longer recruiting

Registration date
13/07/2012

Overall study status
Completed

Last Edited
07/02/2017

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
12264

Study information

Scientific Title

Metformin improves Endothelial function, endothelial progenitor cells and cardiovascular Risk factors In Type 1 diabetes (MERIT study)

Acronym
MERIT

Study objectives
The aim is to examine the mechanism behind the beneficial cardiovascular effects of metformin. This will be achieved by studying the effect of metformin on endothelial progenitor cells (EPCs), their in vitro function and endothelial function in patients with type 1 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - Sunderland, 12/04/2012, ref: 12/NE/0044

Study design
Observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 1 diabetes and cardiovascular disease

Interventions
Patients will be assessed before and after metformin therapy. Prior to commencement of metformin patients will undergo 6 weeks running in period to monitor their glycaemia and exclude presence of hypo-unawarness. During the 8 week study with metformin 500mg patients will aim to achieve unchanged glucose levels. This may require a reduction of insulin doses for the time of the study. The vascular assessment will include measurement of EPCs from peripheral blood, cultured early EPCs and their function in vitro and RNA studies. Patients will have their endothelial function assessed by EndoPAT.

Follow Up Length: 3 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. EPCs
2. Hill Colony Assay
3. Endothelial function

Measured before and after metformin therapy

Key secondary outcome(s))
No secondary outcome measures

Completion date
01/04/2015

Eligibility

Key inclusion criteria
1. Type 1 diabetes mellitus
2. Aged 16 years or over
3. HbA1c <= 8.5
4. Duration of diabetes of at least 5 years
5. Stable diabetes control for at least 2 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Glomerular filtration rate (GFR) < 45 ml/ min/ 1.73m2
2. Woman of childbearing age planning pregnancy
3. Pregnancy and/or lactation
4. Proliferative diabetic retinopathy
5. Cardiovascular disease/ischemic heart disease (IHD)
6. Peripheral vascular disease
7. Cerebrovascular accident (CVA) or transient ischemic attack (TIA)
8. Suspected hypoglycaemia unawareness
9. Impaired cognitive function/ unable to give informed consent
10. History of lactic acidosis
11. Contraindications to metformin
12. History of alcohol problem or drug abuse

Date of first enrolment
28/05/2012

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Gateshead Health NHS Foundation Trust
Gateshead
United Kingdom
NE9 6SX

Sponsor information

Organisation
Gateshead Health NHS Foundation Trust (UK)

ROR
https://ror.org/01aye5y64

Funder(s)

Funder type
Charity

Funder Name
Diabetes Research & Wellness Foundation (UK)

Alternative Name(s)
Diabetes Research & Wellness Foundation, Diabetes Research and Wellness Foundation UK, DRWF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/08/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes