

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

☐ Prospectively registered

☐ Protocol

Registration date
13/07/2012

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
07/02/2017

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Fahad Wali Ahmed

Contact details

Gateshead Health NHS Foundation Trust
Department of Endocrinology
Queen Elizabeth Hospital
Sheriff Hill
Gateshead
United Kingdom
NE9 6SX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Other

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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-unawareness. 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 measure

1. EPCs
2. Hill Colony Assay
3. Endothelial function

Measured before and after metformin therapy

Secondary outcome measures

No secondary outcome measures

Overall study start date

28/05/2012

Completion date

01/04/2015

Eligibility

Key inclusion criteria

1. Type 1 diabetes mellitus
2. Aged 16 years or over
3. HbA1c \leq 8.5
4. Duration of diabetes of at least 5 years
5. Stable diabetes control for at least 2 months

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

46

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

England

United Kingdom

Study participating centre

Gateshead Health NHS Foundation Trust

Gateshead

United Kingdom

NE9 6SX

Sponsor information

Organisation

Gateshead Health NHS Foundation Trust (UK)

Sponsor details

Queen Elizabeth Hospital

Sheriff Hill

Gateshead

England

United Kingdom

NE9 6SX

+44 (0)191 482 0000

contact.qe@ghnt.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.gatesheadhealth.nhs.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

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

Study outputs

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