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Insulin resistance in type 1 diabetes

Submission date	Recruitment status	[ ] Prospectively registered
23/10/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/11/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/11/2016	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 1 diabetes often develops in childhood and puberty . Insulin resistance, an indication of type 2 diabetes that develops in older people (particularly those that are sedentary and/or overweight) a have been increasingly recognized in children and young adults with type 1 diabetes. The exact cause of insulin resistance in type 1 diabetes is still unknown especially that some studies demonstrated that it can coexist in spite of good blood glucose (sugar) levels. Insulin resistance has been linked with increased cardiovascular disease, such as heart disease and stroke, in type 1 diabetics .Among the markers (molecules find in the body) recently linked to insulin resistance in type 2 diabetes is serum Fetuin. Fetuin is a type of protein secreted by the liver. Studies have showed that it can inhibit (block) insulin receptor in rodents. Metformin is an oral glucose-lowering (hypoglycemic) agent that is known for its insulin sensitizing (increasing the body's reaction to insulin) action . Some studies showed that this drug can lead to a decrease in the dose of insulin required and a loss of weight in insulin resistant type 1 diabetics. The aim of this study was to assess serum fetuin level in people with type 1 diabetes who were screened (tested) for insulin resistance and test the effect of metformin therapy on this relation

Who can participate?
Men aged over 18 and diagnosed with type 1 diabetes.

What does the study involve?
There are two phases to this study. In the first phase, participants are tested to see whether they are insulin resistant. Those that are identified as being insulin resistant are then given metformin twice a day for three months in addition to their usual treatment. They all undergo tests before they start treatment and after the three months treatment is complete. These tests check to see how metformin might affect insulin resistance, control of glucose levels in the blood and the weight of the participants.

What are the possible benefits and risks of participating?
Participants will benefit from the possible beneficial effects on their weight , glycemic control (control of blood glucose levels) and required daily insulin dose . There is no specific reported adverse events in type 1 diabetics who receive metformin therapy . Metformin have common side effects as gastrointestinal upset which is reported for type 2 diabetics. Additionally it will not be given to any participant with poor kidney function.

Where is the study run from?
Ain-Shams University Hospitals Diabetes Outpatient Clinic (Egypt)

When is the study starting and how long is it expected to run for?
March 2013 to July 2014

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Yara Eid

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1491

Study information

Scientific Title
Effect of metformin therapy on serum fetuin levels in insulin resistant type 1 diabetics

Study objectives
To determine the relationship between serum fetuin and insulin resistance in type 1 diabetic patients and the effect of short-term metformin therapy on this relationship.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ain-Shams University -Faculty of Medicine-Research Ethics Committee, 21/02/2013, ref: FWA00006444
FMASU 1491/2013

Study design
Single-arm prospective open label interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Type 1 diabetes

Interventions
Type 1 patients eligible for the study were screened for insulin resistance. Subjects with documented insulin resistance were given 1mg metformin twice daily for three months as an add-on to their insulin regimen. Parameters were assessed before intervention and directly at the end of 3 months.

These parameters included:
1. Demographic: BMI , blood pressure ,waist circumference , waist /hip ratio, insulin units /kg , the method of assessment is physical examination and history taking at the basal visit prior to intervention and after 3 months of intervention.
2. Laboratory: Fasting , 2-hour postprandial blood glucose level , glycated-hemoglobin percent (HbA1c) % ,lipid profile: total cholesterol, TG, HDL, LDL , highly sensitive CRP (hs-CRP), measurement of serum fetuin level and calculation of estimated glucose disposal rate.

There was no control arm as all patients with insulin resistance received the same intervention and the outcomes were observed.

Intervention Type
Drug

Primary outcome measure
Effect of metformin therapy on fetuin level in insulin resistant type 1 diabetics

Assessed before assessed before intervention and again at 3 months.

Secondary outcome measures
1. Effect of metformin therapy on insulin resistance surrogate (eGDR)
2. Glycemic control (HbA1c%)
3. BMI
4. Weight
5. Insulin dose
6. HsCRP as a marker of cardiovascular risk

All assessed before assessed before intervention and again at 3 months.

Overall study start date
01/03/2013

Completion date
10/07/2014

Eligibility

Key inclusion criteria
T1DM male subjects ≥ 18 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
40 patients

Key exclusion criteria
Subjects with other chronic diseases (such as end-stage liver disease and end-stage renal disease), collagen diseases, malignancies and subjects with any other endocrinopathy (e.g. Cushing's syndrome and acromegaly) or taking any medications (e.g. thiazide diuretics or steroids) that may affect insulin resistance.

Date of first enrolment
01/03/2013

Date of final enrolment
01/02/2014

Locations

Countries of recruitment
Egypt

Study participating centre
Ain-Shams University Hospitals Diabetes Outpatient Clinic
Ramsis Street
Abbassia Square
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Sponsor information

Organisation
Ain-Shams University Research Ethical committee

Sponsor details
Faculty of medicine - Ramsis street , abbassia square
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Sponsor type
Other

ROR
https://ror.org/00cb9w016

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request