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Quantitative analysis of retinal microcirculation in children with type 1 diabetes

Submission date
17/03/2019

Recruitment status
No longer recruiting

Registration date
21/03/2019

Overall study status
Completed

Last Edited
02/03/2022

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Diabetes mellitus is a life-long condition where a person is unable to control their blood sugar levels. There are two main types of diabetes, type 1 (around 10% of cases) and type 2. In type 1 diabetes (T1DM) the immune system attacks specialised cells in the pancreas called beta-cells (which are responsible for producing the hormone insulin). This means that the sufferer is unable to produce enough insulin to effectively control their blood sugar levels and so regularly inject insulin in order to keep their blood sugar levels in a healthy range. DM is also one of the most common chronic disease among children. This chronic disease could affect both anterior and posterior ocular structures of those children. Diabetic retinopathy (DR), which is the most common microvascular complication of type 1 DM, is still one of the leading causes of blindness even in developed countries. Recent technological advances mean that systems are now able to measure the retinal blood vessel density and flow of retina (posterior layer of eyeball that contains cells sensitive to light) in humans with a contrast-free technique. The aim of this study is to compare the retinal microcirculation in children with T1DM and healthy children to look at whether there is a link between diabetes and retinal microcirculation.

Who can participate?
Children aged 6-18 who have T1DM and no eye problems, and healthy children of the same age.

What does the study involve?
All participants attend a single study visit. At the visit, all participants undergo a comprehensive eye examination where optical coherence tomography angiography images are taken of the eye in order to assess retinal microcirculation. Participants who have diabetes also have a number of blood samples taken in order to assess their current blood sugar control. At the end of the study visit, the results between the two groups of participants are compared. In addition, the blood sugar control and length of time the diabetic participants have been diabetic is compared to the results from the eye exams.

What are the possible benefits and risks of participating?
There are no direct benefits involved with participating. There is a small risk of pain or bruising from blood tests.

Where is the study run from?
1. Ulucanlar Eye Training and Research Hospital (Turkey)
2. Children's Health and Disease Training and Research Hospital (Turkey)

When is the study starting and how long is it expected to run for?
June 2017 to March 2018

Who is funding the study?
Investigator initiated and funded (Turkey)

Who is the main contact?
Merve Inanc, M.D.
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
16-1068

Study information

Scientific Title
Changes in retinal microcirculation precede the clinical onset of diabetic retinopathy in children with type 1 diabetes mellitus

Study objectives

The abnormal glucose metabolism in type 1 diabetes mellitus (DM) affects the retinal microcirculation in children with well-controlled Type 1 DM for whom the duration of DM and glycemic control had been well documented.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/04/2016 by Ethics Committee of the Ankara Numune Training and Research Hospital, Talatpasa boulevard, Ulku street, number: 5, Tel: +90 (0)312 508 5910, Email: aneahetikkurul@gmail.com, ref: E-16-1068

Study design
Prospective cross-sectional and case-control study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Retinal microcirculation and vessel density

Interventions
All participants attend a single study visit, at which they undergo a comprehensive ophthalmic examination including best corrected visual acuity tests using the Snellen chart, intraocular pressure measurements by a pneumotonometer, slit-lamp biomicroscopy, and dilated fundus examination. High-quality colour stereoscopic fundus photographs are also taken. Refraction measurements are performed by using the same automatic refractor-keratometer device (Canon RF-K2, Japan). Moreover, blood samples are taken for the pre-prandial blood glucose and glycosylated hemoglobin (HbA1c) levels on the same day for the diabetic cases. The duration of DM and the HbA1c levels were recorded. Moreover, to quantify the vessel density and retinal microcirculation, the AngioVue device (Version 2017.1.0.151 of the RTVue XR Avanti, Opto-Vue, Inc, Fremont, CA, USA) was used in the study.

Intervention Type
Other

Primary outcome(s)
Retinal microcirculation parameters and vessel density indexes are measured using an optical coherence tomography angiography device (the AngioVue device, Version 2017.1.0.151 of the RTVue XR Avanti, Opto-Vue, Inc, Fremont, CA, USA) at the single visit:
1. Foveal zone vessel density: the area of the small circle, with a diameter of 1 mm
2. Parafoveal zone vessel density: the area of the middle circle, with a diameter of 3 mm
3. Perifoveal zone vessel density: the area of the outer circle with a diameter of 6 mm.
4. Foveal avascular zone area
5. Foveal avascular zone perimeter

6. Acircularity index of foveal avascular zone: the ratio of the perimeter of the foveal avascular zone
7. Foveal density (FD-300): vessel density in 300 microns around the foveal avascular zone

Key secondary outcome(s))
All measurements taken at the single visit (on the day of ocular examination):
1. Duration of diabetes mellitus (since the diagnosis of type 1 diabetes mellitus) measured using medical records
2. Pre-prandial blood glucose and glycosylated hemoglobin (HbA1c) levels measured using blood samples in the diabetic group

Completion date
30/03/2018

Eligibility

Key inclusion criteria
Diabetic patient inclusion criteria:
1. Aged 6-18 years
2. Male and female
3. No previous known macular or other retinal changes,
4. No ocular problem other than spherical or cylindrical refractive errors ≤ 1.00 diopter
5. No systemic disease except than Type 1 DM
6. The best-corrected vis6.ual acuity according to Snellen chart equal or greater than 20/20
7. A pre-prandial blood glucose level ≤ 100 mg/dl under insulin treatment
8. Patients who had information about the duration of diabetes mellitus.

Control participant inclusion criteria:
1. Aged 6-18 years
2. Male and female
3. No systemic disease
4. No ocular problem other than spherical or cylindrical refractive errors ≤ 1.00 diopter
5. Best-corrected visual acuity according to Snellen chart equal or greater than 20/20

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
18 years

Sex

All

Key exclusion criteria
All participants:
1. Strabismus
2. Nystagmus
3. History of previous ocular surgery or laser treatment
4. Trauma or uveitis
5. Corneal diseases such as corneal scar
6. Fundus abnormalities including diabetic retinopathy/maculopathy
7. Optic nerve diseases and glaucoma
8. Neurological disease or other diseases of the visual pathways
9. Ocular media opacities including cataract
10. Use of chronic topical medication
11. Those who are not sufficiently cooperative for optical coherence tomography angioraphy examinations

Date of first enrolment
15/06/2017

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Türkiye

Study participating centre
Ulucanlar Eye Training and Research Hospital
Ulucanlar Street Number:59, 06240
ankara
Türkiye
06240

Study participating centre
Sami Ulus Children's Health and Disease Training and Research Hospital
Babur Street, Number: 44
ankara
Türkiye
06230

Sponsor information

Organisation
Ulucanlar Eye Training and Research Hospital

ROR
https://ror.org/045d4f586

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Merve Inanc M.D. (mrvn88@hotmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2019	02/03/2022	Yes	No