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Evaluation of cornea and lens clarity in children with diabetes mellitus

Submission date	Recruitment status	[_] Prospectively registered
14/03/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/03/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/10/2018	Eye Diseases	

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. Having T1DM increases a person's risk of developing problems with their eyesight, such as cataracts (a condition in which the natural lens inside the eye can become cloudy and hard, leading to visual problems). Recent technological advances mean that systems are now able to measure the clarity of a person's lens and cornea (transparent layer forming the front of the eye). The aim of this study is to compare the cornea and lens clarity in children with T1DM and healthy children to look at whether there is a link between diabetes and cornea and lens clarity.

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 special photographs are taken of the eye in order to assess the clarity of the lens and cornea. 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 2016 to January 2017

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

Who is the main contact?
Professor Kemal Tekin
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
156125

Study information

Scientific Title
Objective evaluation of corneal and lens clarity in children with type 1 diabetes mellitus

Study objectives
The abnormal glucose metabolism in diabetes mellitus (DM) affects the corneal and lens clarity in children with well-controlled Type 1 DM for whom the duration of DM and glycaemic control had been well documented.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Ankara Numune Training and Research Hospital, 12/04/2016

Study design
Prospective case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Corneal and lens clarity

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 (20 feet), intraocular pressure measurements by a pneumotonometer, slit-lamp biomicroscopy, and dilated fundus examination. High-quality colour stereoscopic fundus photographs are taken of all participants. Refraction measurements are performed by using 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, Pentacam analysis to determine the cornea and lens densitometry was performed. Each participants underwent two consecutive Pentacam measurements: The first is performed without pupil dilatation to evaluate the corneal densitometry values and the second was performed after a pupil dilatation to evaluate the lens densitometry and thickness values.

Intervention Type
Other

Primary outcome measure

Corneal and Lens densitometry values are measured using a Scheimpflug camera (Pentacam HR) on the study visit.

Secondary outcome measures
Correlations between the duration of diabetes and densitometry measurements of the cornea or lens are calculated using blood testing and eye examinations on the study visit.

Overall study start date
01/06/2016

Completion date
01/01/2017

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

Age group
Child

Lower age limit
6 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
110

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 Scheimpflug system examinations

Date of first enrolment
01/07/2016

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
Türkiye

Study participating centre
Ulucanlar Eye Training and Research Hospital
Ulucanlar Street Number:59
Ankara
Türkiye
06230

Study participating centre
Children's Health and Disease Training and Research Hospital
Babur Street, Number: 44
Ankara
Türkiye
06240

Sponsor information

Organisation
Ulucanlar Eye Training and Research Hospital

Sponsor details
Ulucanlar Street Number: 59
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Sponsor type
Hospital/treatment centre

Website
http://ulucanlargoz.gov.tr/

ROR
https://ror.org/045d4f586

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal between March 2017- March 2018.

Intention to publish date
31/03/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Kemal Tekin, kemal_htepe@hotmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2017		Yes	No