

Evaluation of cornea and lens clarity in children with diabetes mellitus

Submission date 14/03/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/03/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/10/2018	Condition category Eye Diseases	<input type="checkbox"/> 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. 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

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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.

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 visual 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 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

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 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