

Spectacles for correcting irregular astigmatism in patients with keratoconus

Submission date 13/03/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/03/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/04/2023	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Keratoconus occurs when the cornea (front surface of the eye) thins and bulges outward into a cone shape, causing blurred vision. This study aims to create spectacle lenses that correct irregular astigmatism for keratoconic patients. As advanced keratoconic patients find difficulty in their daily life when they cannot wear their contact lenses, this study will be a step towards developing spectacles that can maintain a reasonable visual acuity. The study addresses the visual side effects of the resultant distortion with the development of spectacle lenses that can correct non-orthogonal astigmatism. This is not possible with current spectacle lens manufacturing techniques, leaving patients with this condition entirely dependent on contact lenses, or in severe cases, corneal transplants, to achieve reasonable visual acuity.

Who can participate?

Keratoconus patients aged 18 years and over

What does the study involve?

Visual acuity is measured at a single visit with no follow-up.

What are the possible benefits and risks of participating?

Participation has no direct benefit, and risks are minimal as it is like trying a pair of glasses.

Where is the study run from?

Royal Liverpool University Hospital

When is the study starting and how long is it expected to run for?

July 2021 to December 2022

Who is funding the study?

1. Fight for Sight (UK)
2. Keratoconus Group (UK)

Who is the main contact?

Dr Ahmed Abass, amfabass@liverpool.ac.uk

Contact information

Type(s)

Principal investigator

Contact name

Dr Ahmed Abass

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

282471

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

UoL001582, IRAS 282471, CPMS 49194

Study information

Scientific Title

Spectacles for correcting irregular astigmatism in keratoconic patients

Study objectives

An earlier analytical study indicated that the higher the degree of non-orthogonal astigmatism the larger the benefit to the patient's visual acuity (Abass, Lopes et al. 2019). This study will assess this prediction and identify those candidates who stand to benefit most from using non-orthogonal lenses. Those candidates will be identified based on their topography power maps. As conventional topographers' software packages are measuring orthogonal astigmatism only, a special custom-built MATLAB code will be developed to locate the non-orthogonal astigmatism axes and determine if the patient is a good candidate for this treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/07/2021, London - Bromley Research Ethics Committee (Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, UK; +44 (0)2071048118, +44 (0)2071048140, +44 (0)2071048016; bromley.rec@hra.nhs.uk), ref: 21/PR/0561

Study design

Prospective controlled observational study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Keratoconus

Interventions

Visual acuity is measured at a single visit with no follow-up.

Intervention Type

Device

Phase

Not Applicable

Primary outcome(s)

Visual acuity in LOGMAR at refraction (using both letters and lines) measured at a single visit

Key secondary outcome(s)

1. Keratometry measured using a keratometer at a single visit
2. Corneal thickness measured using a Pentacam tomographer at a single visit
3. Corneal profile measured using a Pentacam tomographer at a single visit
4. Aberrometry measured using an aberrometer at a single visit

Completion date

31/12/2022

Eligibility

Key inclusion criteria

Keratoconus patients aged 18 years and over

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

15

Key exclusion criteria

1. Patients unable to fixate on a target
2. Patients under 18 years old
3. Patients with other ocular diseases
4. Pregnant patients
5. Patients with a corneal scar or fibrosis

Date of first enrolment

15/02/2022

Date of final enrolment

30/06/2022

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Royal Liverpool University Hospital

W Derby Street

Liverpool

United Kingdom

L7 8YA

Sponsor information

Organisation

University of Liverpool

ROR

<https://ror.org/04xs57h96>

Funder(s)

Funder type

Charity

Funder Name

Fight for Sight UK

Alternative Name(s)

Fight for Sight, Fight for Sight (UK)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Keratoconus Group

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No