

# Spectacles for correcting irregular astigmatism in patients with keratoconus

<b>Submission date</b> 13/03/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/03/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/04/2023	<b>Condition category</b> 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](mailto:amfabass@liverpool.ac.uk)

# Contact information

## Type(s)

Principal Investigator

## Contact name

Dr Ahmed Abass

## ORCID ID

<http://orcid.org/0000-0002-8622-4632>

## Contact details

Department of Mechanical, Materials and Aerospace Engineering  
School of Engineering, University of Liverpool  
Brownlow Hill  
Liverpool  
United Kingdom  
L69 3GH  
+44 (0)151 794 5229  
[a.abass@liverpool.ac.uk](mailto:a.abass@liverpool.ac.uk)

# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

282471

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

**Secondary study design**

Cross sectional study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

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

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

08/07/2021

**Completion date**

31/12/2022

## Eligibility

**Key inclusion criteria**

Keratoconus patients aged 18 years and over

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

15

**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**

England

United Kingdom

**Study participating centre**

**Royal Liverpool University Hospital**  
W Derby Street  
Liverpool  
United Kingdom  
L7 8YA

## **Sponsor information**

### **Organisation**

University of Liverpool

### **Sponsor details**

Research Support Office  
2nd Floor Block D Waterhouse Building  
3 Brownlow Street  
Liverpool  
England  
United Kingdom  
L69 3GL  
+44 (0)151 794 8739  
sponsor@liverpool.ac.uk

### **Sponsor type**

University/education

### **Website**

<https://www.liverpool.ac.uk/>

### **ROR**

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

## **Funder(s)**

### **Funder type**

Charity

### **Funder Name**

Fight for Sight UK

### **Alternative Name(s)**

Fight for Sight

### **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

**Publication and dissemination plan**

The results of this study will be published in a research paper

**Intention to publish date**

31/12/2023

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No