ISRCTN15964758 https://doi.org/10.1186/ISRCTN15964758

Spectacles for correcting irregular astigmatism in patients with keratoconus

Submission date	Recruitment status	[ ] Prospectively registered
13/03/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/03/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/04/2023	Eye Diseases	[ ] 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

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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
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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?
HRA research summary			28/06/2023	No	No