

Corneal Collagen Cross-linking with Riboflavin (C3R) with orthokeratology

Submission date 14/02/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/03/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/06/2017	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Chad Rostron

Contact details
Duke Elder Eye Unit (Moorfields Eye Department)
St George's Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT
+44 (0)20 8725 2325
rostron@sgul.ac.uk

Additional identifiers

Protocol serial number
CHAR1004

Study information

Scientific Title
Pilot study of corneal collagen cross-linking with riboflavin (C3R) with pre-operative orthokeratology

Acronym

C3R

Study objectives

To assess whether orthokeratology using a specifically designed contact lens could enhance the corneal flattening effect of collagen cross-linking by ultraviolet (UV) light with riboflavin (C3R) and reduce any pre-existing astigmatism and/or myopia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Moorfields and Whittington Hospitals Research Ethics Committee, 01/12/2006, ref: 06/Q0504 /106

Study design

Pilot randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Corneal ectasia

Interventions

Corneal collagen cross-linking with riboflavin and UV light, plus or minus orthokeratology.

Pre-operatively:

10 patients will be fitted with a specially-made contact lens, which they will need to wear for one week prior to the surgical procedure, in an attempt to change the irregular profile of the cornea prior to undergoing the corneal collagen cross-linking (C3R) treatment. The other 10 patients will not be fitted with any kind of lens.

Surgical procedure:

The surgery will be performed on all 20 patients. Local anaesthesia with anaesthetic eye drops will be utilised. The procedure involves removal of the superficial cell layer of the cornea (epithelium) and then instilling riboflavin eye drops into the eye every three minutes for 30 minutes, until the surgeon judges that an adequate level has been obtained. At that point the ultraviolet light will be directed onto the cornea for 30 minutes to produce collagen cross-linking. Cross-links are small bridges between the fibres in the cornea which strengthen the cornea. Total time for the procedure will be about 1 hour 15 minutes to 1 hour 30 minutes.

Intervention Type

Procedure/Surgery

Primary outcome(s)

The difference in the pre- and post-operative:

1. Unaided visual acuity

2. Best corrected visual acuity
3. Refraction

Key secondary outcome(s)

Corneal topographical profile, measured pre-operatively and at one and six months post-operatively.

Completion date

05/09/2008

Eligibility

Key inclusion criteria

Corneal ectasia (keratoconus, pellucid marginal degeneration or post-excimer laser corneal ectasia) in patients intolerant or with limited tolerance of contact lenses. The only other options would be INTACS or corneal grafting.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Age less than 18 years or greater than 40 years
2. Maximal K greater than 60D
3. Minimal Oculus Pentacam pachymetry less than 400 μ , to avoid the risk of endothelial damage
4. Evidence of other corneal disease in the eye to be treated (e.g., herpes simplex keratitis)
5. Women who are pregnant or nursing at the time of the initial treatment
6. Presence of significant central corneal opacity
7. Patients unwilling to not wear their rigid contact lenses in the eye to be treated for at least one month before baseline examination, and for the first six months post-operatively (this will be necessary in order to obtain accurate refraction and keratometry readings)

Date of first enrolment

05/09/2007

Date of final enrolment

05/09/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Duke Elder Eye Unit (Moorfields Eye Department)

London

United Kingdom

SW17 0QT

Sponsor information

Organisation

Moorfields Eye Hospital NHS Foundation Trust (UK)

ROR

<https://ror.org/03zaddr67>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Moorfield Eye Hospital Special Trustees (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration