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# A randomised prospective study to investigate the efficacy of corneal collagen cross linkage with riboflavin (vitamin B2) and ultraviolet A light (UVA) (370nm) to halt the progression of keratoconus

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 28/09/2007 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 28/09/2007 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 12/12/2013 | Eye Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N0013180304

# Study information

### Scientific Title

### Study objectives
The aim is to determine whether the progression of keratoconus can be halted by strengthening the cornea by cross-linkage of its collagen using ultraviolet A (UVA) light and riboflavin (vitamin B) as a photosensitizer.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomized, bilateral-controlled, prospective clinical investigation

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Keratoconus

### Interventions
Randomized, bilateral-controlled, prospective clinical investigation (one eye acts as control while opposite acts as study) whereby riboflavin eye drops are applied and ultraviolet A light is shone into corneal surface. Study group undergoes full ophthalmic examination of both eyes, a full refraction test, corneal topography, keratometry, corneal pachymetry and applanation tonometry, at 1 day, week, month then month 3, 6, 12 & 18.

### Intervention Type
Supplement

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
riboflavin (vitamin B2)

### Primary outcome measure
To determine whether Riboflavin/ UVA corneal cross-linkage can prevent the progression of keratoconus. The non-treated eye will act as a control.

### Secondary outcome measures
To determine whether Riboflavin/UVA corneal cross-linkage can reverse some of the bowing of the cornea caused by keratoconus. To determine whether non-treated eyes have progression of keratoconus compared to those eyes which underwent cross-linkage treatment.

### Overall study start date
05/06/2006

### Completion date
04/12/2007

## Eligibility

### Key inclusion criteria
36 patients with moderate bilateral keratoconus recruited from the corneal and contact lens clinics at Guy's and St. Thomas' NHS Foundation Trust. Inclusion criteria:
1. Age 18 to 70
2. Must fully understand the investigative nature of the study
3. Moderate to advanced bilateral keratoconus
4. No known allergies to pre- and post-operative medications
Willingness to attend for follow-up examinations

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Not Specified

### Target number of participants
36

### Key exclusion criteria
1. Age below 18
2. Other pre-existing ophthalmic pathology
3. Previous ophthalmic surgery
4. Unilateral keratoconus
5. Severe keratoconus in which the cornea is so distorted that accurate refractive and corneal measurements cannot be obtained (in these eyes data confirming stability or progression is not possible)

### Date of first enrolment
05/06/2006

### Date of final enrolment
04/12/2007

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Opthalmology**
London
United Kingdom
SE1 7RH

## Sponsor information

### Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

### Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

### Sponsor type
Government

### Website

http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Government

**Funder Name**
Guy's and St. Thomas' NHS Foundation Trust

**Funder Name**
Own account

**Funder Name**
NHS R&D Support Funding

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/11/2011 | | Yes | No |