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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