

# Genealogy and quality of life in patient with keratoconus

<b>Submission date</b> 24/12/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/02/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/08/2020	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Keratoconus is an eye condition in which the cornea (the clear dome-shaped “window” of the eye) becomes weaker, thinner and changes shape over time. It is usually diagnosed in teenagers and young adults. What causes the condition is not known, but it is thought possible that its passed down through the family (genetic inheritance) and it’s more common in people with allergic diseases (for example, asthma). Many cases can be managed by wearing contact lenses or glasses, but very advanced cases may only be treatable with a corneal transplant (keratoplasty). We want to investigate both the possible inheritance pattern of the disease and the quality of life for patients for which keratoconus is being managed without surgery.

### Who can participate?

Any patient with a keratoconus condition and their relatives.

### What does the study involve?

Participants take part in an ophthalmologic (eye) examination and a corneal topography (a computer-assisted non-invasive technique that creates a topological map of the cornea). They are also asked to fill in a questionnaire about their quality of life.

### What are the possible benefits and risks of participating?

Potential benefits to participation in this study include identifying keratoconus in relatives of the patient, resulting in earlier and more successful treatment. There is no risk to participating.

### Where is the study run from?

Hotel-Dieu Hospital, Department of ophthalmology, Paris (France)

### When is the study starting and how long is it expected to run for?

January 2015 to June 2015

### Who is funding the study?

1. University Sorbonne Paris Cité (France)
2. Assistance Publique-Hopitaux de Paris (France)

Who is the main contact?  
Professor Jean-Louis Bourges

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Jean-Louis Bourges

**Contact details**  
Hotel-Dieu Hospital  
Department of Ophthalmology  
1, Place du Parvis Notre-Dame  
Paris  
France  
75004

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
2014-A01964-43

## Study information

**Scientific Title**  
Genealogy and quality of life in patient with keratoconus: a cross-sectional cohort study

**Acronym**  
KCQoL

**Study objectives**  
Corneal imaging and therapeutic strategies are continuously improving. Keratoconus can now be detected earlier now than a decade ago. The evolution can now be tackled whereas the cost effectiveness of treatments should be rationalized as much as possible. Thus, the prevalence and the real quality of life of the keratoconus patients should both be evaluated again.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Société Francaise d'Ophtalmologie (SFO)

**Study design**

Cross-sectional cohort study prospective non controlled single-centre

**Primary study design**

Observational

**Secondary study design**

Cross sectional study

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life

**Participant information sheet****Health condition(s) or problem(s) studied**

Keratoconus

**Interventions**

We plan to submit patients to the VF25 questionnaire for Quality of Life and find out if any relatives also have the disease.

**Intervention Type**

Other

**Primary outcome measure**

VF25 QoL score

**Secondary outcome measures**

1. Presence or absence of keratoconus in relatives
2. Age of parents

**Overall study start date**

01/01/2015

**Completion date**

01/06/2015

**Eligibility****Key inclusion criteria**

Patient with keratoconus based upon criteria from corneal topography and their relatives

**Participant type(s)**

Patient

**Age group**

Other

**Sex**

Both

**Target number of participants**

200

**Total final enrolment**

101

**Key exclusion criteria**

Patients with keratoplasty

**Date of first enrolment**

01/01/2015

**Date of final enrolment**

01/06/2015

**Locations****Countries of recruitment**

France

**Study participating centre****Hotel-Dieu, Paris**

Department of Ophthalmology

1 place du parvis Notre-Dame

Paris

France

75004

**Sponsor information****Organisation**

Sorbonne Paris Cité

**Sponsor details**

Faculty of Medicine

Paris Descartes

Assistance Publique-Hopitaux de Paris

Paris

France

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**Sponsor type**

University/education

**Website**

<http://www.sorbonne-paris-cite.fr/en>

**ROR**

<https://ror.org/001z21q04>

**Organisation**

Hospital Hotel-Dieu

**Sponsor details**

Department of Ophthalmology

1, Place du Parvis Notre-Dame

Paris

France

75004

+33142348234

[cs-oph.rdv@htd.aphp.fr](mailto:cs-oph.rdv@htd.aphp.fr)

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.aphp.fr/hopital/hotel-dieu/>

**Funder(s)**

**Funder type**

University/education

**Funder Name**

Université Sorbonne Paris Cité (France)

**Funder Name**

Assistance Publique-Hopitaux de Paris (France)

**Funder Name**

Association Ophtalmologie Cochin (AOC)

# Results and Publications

## Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Other

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2020	14/08/2020	Yes	No