

Genealogy and quality of life in patient with keratoconus

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| Submission date 24/12/2014 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 11/02/2015 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 14/08/2020 | Condition category 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
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Department of Ophthalmology
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Additional identifiers

Protocol serial number
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

Study type(s)

Quality of life

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(s)

VF25 QoL score

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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

ROR

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

Organisation

Hospital 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

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

Other

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/07/2020 | 14/08/2020 | Yes | No |