Clinical Benefits of Color LED Topography in Keratoconus Screening

Published: 30-07-2012
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To demonstrate that CLT is more sensitive for keratoconus detection compared to other corneal topography methods.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Eye disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON37070

Source
ToetsingOnline

Brief title
CLT of keratoconus

Condition

- Eye disorders NEC

Synonym
keratoconus

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis Rotterdam.

Intervention

Keyword: color LED topography, keratoconus

Outcome measures

Primary outcome

Keratoconus indices and corneal aberrations

Secondary outcome

NA.

Study description

Background summary

Detection of (subclinical) keratoconus has become increasingly relevant because, for instance, its presence may affect the outcome of keratorefractive procedures. With respect to measuring irregular corneal features, Color LED Topography (CLT) is a potentially superior technology compared to other topography techniques.

Study objective

To demonstrate that CLT is more sensitive for keratoconus detection compared to other corneal topography methods.

Study design

Observational.

Study burden and risks

This is a non-invasive study, eye drops are not required. Risks are negligible and burden is low. Measurements are performed at the time of a (single) regular visit and take about 15 minutes extra time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Informed consent.
Healthy volunteers (cataract patients) >= 18 years of age.
Patients with keratoconus >= 12 years of age.

Exclusion criteria

Patients not able to steadily keep their eye open during the required fixation period (15 s).
Morbus Terrien.
Pellucid marginal degeneration.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-11-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	30-07-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL40559.078.12