

Therapeutic applications of soft contact lenses in severe dry eye with chronic graft-versus-host disease

Submission date 30/11/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/01/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/01/2021	Condition category Eye Diseases	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

001

Study information

Scientific Title

Therapeutic applications of soft contact lenses in severe dry eye with chronic graft-versus-host disease

Study objectives

Bandage contact lenses have favourable effects on the ocular surface disease status in severe dry eye patients with chronic Graft-Versus-Host Disease (cGVHD).

Ethics approval required

Old ethics approval format

Ethics approval(s)

US Food and Drug Administration (FDA) approved contact lens material used for the study. Therapeutic contact lenses are not regarded as medical devices in Japan. According to our regulations, when contact lenses are deemed essential for therapeutic purposes by an ophthalmologist, permission from the university or hospital is not required.

Study design

Retrospective, consisting of chart review of GVHD patients who received therapeutic contact lenses wear. Please note that chart reviews started in September 1, 2006 and will be finalised by spring next year.

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Chronic graft versus host disease

Interventions

Silicone hydrogel Contact Lens use. Patients wore contact lenses continuously and replaced their contact lenses for every week to once in four weeks. Only patients with more than six months of follow up were included.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Pain relief

Key secondary outcome(s))

Vital staining score

Completion date

30/04/2007

Eligibility

Key inclusion criteria

1. Severe cGVHD dry eye subjects with fibrotic lid changes and trichiasis refractory to treatment with non-preserved artificial tears
2. Autologous serum eye drops
3. Bilateral punctal occlusion

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Total final enrolment

7

Key exclusion criteria

1. Mild cGVHD patients
2. cGVHD

Date of first enrolment

01/09/2006

Date of final enrolment

30/04/2007

Locations

Countries of recruitment

Japan

Study participating centre

Shinanomachi 35 Shinjuku ku

Tokyo

Japan

160-8582

Sponsor information

Organisation

Ciba Vision (Japan)

ROR

<https://ror.org/01k1ftz35>

Funder(s)**Funder type**

Other

Funder Name

Contact lenses were donated by CIBA vision. Costs incurred by vital staining, and

Funder Name

slit lamp examinations were covered by social insurance.

Results and Publications**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?
Abstract results	results presented at ARVO	01/05/2007	14/01/2021	No	No