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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 occular 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

Secondary study design

Single-centre

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

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 measure

Pain relief

Secondary outcome measures

Vital staining score

Overall study start date

01/09/2006

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

10 patients

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)

Sponsor details

Tennoz Central Tower 13 2-2-24 Higashi Shinagawa Tokyo Japan 140-0002

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junoga1102@yahoo.co.jp

Sponsor type

Industry

Website

http://www.cibavision.jp

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

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?
Abstract results	results presented at ARVO	01/05/2007	14/01/2021	No	No