ISRCTN05106737 https://doi.org/10.1186/ISRCTN05106737

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/01/2007	**Overall study status** Completed	
Last Edited 14/01/2021	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Junko Ogawa

Contact details
Shinanomachi 35 Shinjuku ku
Keio Univ Sch Med
Dept Ophthalmology
Tokyo
Japan
160-8582
-
junoga1102@yahoo.co.jp

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 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
-
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