Study title: A clinical trial to investigate the safety and clinical performance of Hydroxypropyl-Beta-Cyclodextrin 10% w/v Eye Drops in the treatment of dry eye disease.

ISRCTN title: Can eye drops effectively treat dry eye disease?

ISRCTN number: 36213

REC reference: 19/LO/0623

IRAS project ID: 249742

Sponsor details: Warneford Healthcare
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Trial Coordinators: Aspire Pharma Limited
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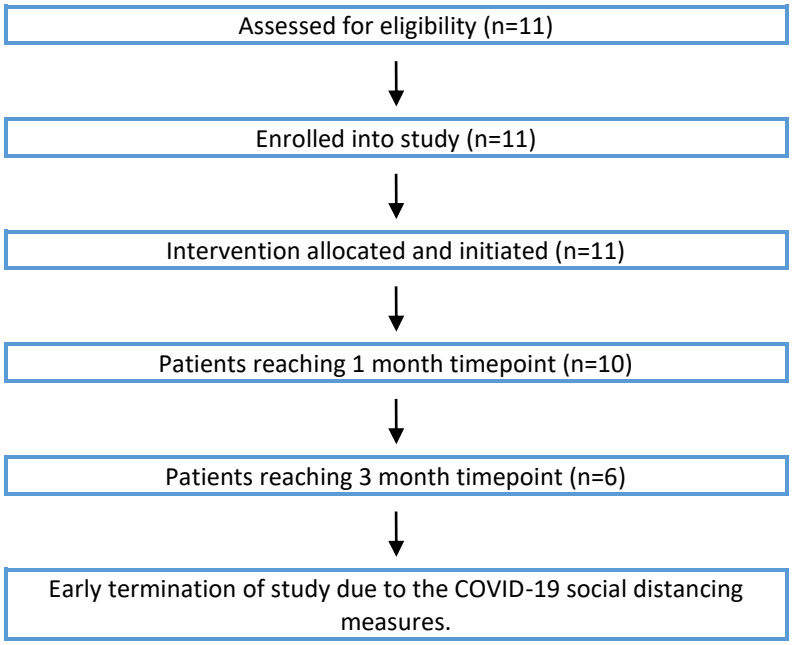
1 PARTICIPANT FLOW CHART

Please find below a summary flow chart showing the participants involved at each stage of the study.



2 BASELINE CHARACTERISTICS

Please see below a summary of demographic of the study population including relevant clinical characteristics and baseline dry eye symptoms.

	Population (n=11)
Mean age (years) (standard deviation)	75.2 (6.29)
Female sex (%)	63.6
Dry eye disease (%)	72.7
Macular degeneration (%)	100.0
Cataracts (%)	72.7
Mean duration of baseline symptoms (%) (standard deviation)	13.40 (9.87)

Baseline symptom	**Population experienced symptom (%)**
Itchy	54.5
Gritty	45.5
Blurry vision	18.2
Stickiness of lids	9.1
Burning	9.1
Tearing	18.2
Tired eyes	45.5
Poor night vision	9.1
Sore eyes	9.1
Redness	9.1
Glare	9.1

3 OUTCOME MEASURES

Primary outcome measures

Outcome measure		**Results**

Recording symptoms and adverse events during each clinical follow up.

Patients reported how often dry eye symptoms were experienced on a scale of 0 to 4 (0 = Never; 1 = Sometimes; 2 = Half of the time; 3 = Most of the time; 4 = Constantly)

	Mean score (standard deviation)			
Visit	**Dryness or grittiness**	**Soreness or irritation**	**Burning/ stinging/ watering**	**Eye fatigue**
Baseline n=11	1.64 (1.02)	1.00 (1.22)	0.73 (0.98)	1.73 (1.25)
1 month n=10	0.80 (0.63)	0.90 (1.16)	0.50 (0.50)	0.90 (0.94)
3 months n=6	0.67 (0.49)	0.67 (0.75)	0.50 (0.49)	1.33 (1.36)

Patients reported how severe the dry eye symptoms were on a scale of 0 to 4 (0 = Not applicable; 1 =Mild; 2 = Moderate; 3 = Severe; 4 = Very Severe)

	Mean score (standard deviation)			
Visit	**Dryness or grittiness**	**Soreness or irritation**	**Burning/ stinging/ watering**	**Eye fatigue**
Baseline n=11	1.56 (0.50)	1.67 (0.75)	2.00 (0.71)	1.88 (0.93)
1 month n=10	1.71 (0.47)	2.00 (0.71)	2.00 (1.00)	2.00 (0.82)
3 months n=6	2.00 (0.00)	2.00 (0.00)	1.67 (0.51)	1.50 (0.48)

A full ocular exam with Optical Coherence Tomography (OCT) at each clinical follow up.

No safety concerns highlighted in the OCT scans.

Clinical performance was measured using patient questionnaire answers regarding a change in baseline for dry eye symptoms at each clinical follow up.

	Mean VAS Score (standard deviation)
Baseline n=11	6.7 (2.12)
1 month n=10	7.6 (1.58)
3 months n=6	7.4 (1.02)

Secondary outcome measures

Outcome measure		**Results**

Quality of life was measured using patient questionnaire answers at each clinical follow up.

Percentage of participants experiencing issues with quality of time aspects over the study period

	Percentage of participants experiencing issues with quality of time aspects			
	Reading	**Using a computer**	**Driving**	**Watching TV**
Baseline n=11	63.6	63.6	18.2	36.4
1 month n=10	40.0	50.0	10.0	50.0
3 months n=6	33.3	16.7	16.7	33.3

<table>
<tr><td></td><td>Percentage of participants who experienced the three eye drops related adverse events</td><td>
<table>
<tr><th></th><th colspan="2">Percentage of side effects</th></tr>
<tr><th>at each timepoint</th><th>1 month</th><th>3 months</th></tr>
<tr><td>Burning</td><td>12.5</td><td>10</td></tr>
<tr><td>Stinging</td><td>43.75</td><td>50</td></tr>
<tr><td>Blurring of vision</td><td>31.25</td><td>20</td></tr>
</table>
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<tr><td colspan="2">Tear film break-up time (TBUT) at each clinical follow up.</td><td>
<table>
<tr><th colspan="3">Mean TBUT score (standard deviation)</th></tr>
<tr><th>Baseline n=11</th><th>1 month n=10</th><th>3 months n=6</th></tr>
<tr><td>7.3 (2.37)</td><td>8.1 (1.97)</td><td>9.3 (1.97)</td></tr>
</table>
</td></tr>
<tr><td colspan="2">Schirmer’s test at each clinical follow up.</td><td>
<table>
<tr><th colspan="3">Mean Schirmer’s score (standard deviation)</th></tr>
<tr><th>Baseline n=11</th><th>1 month n=10</th><th>3 months n=6</th></tr>
<tr><td>7.5 (3.01)</td><td>8.6 (2.84)</td><td>8.8 (1.83)</td></tr>
</table>
</td></tr>
<tr><td colspan="2">Ease of use of the device (in line with the instructions for use) was measured using patient questionnaire answers at each clinical follow up.</td><td>
<table>
<tr><th colspan="2">Mean Ease of use VAS score (standard deviation)</th></tr>
<tr><th>1 month n=10</th><th>3 months n=6</th></tr>
<tr><td>5.8 (3.49)</td><td>6.3 (3.20)</td></tr>
</table>
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4 ADVERSE EVENTS

There were no serious adverse events, anticipated or unanticipated, associated with this trial.

Event by MedDRA System Organ Class	Month 1	Month 2	Month 3	Total
Eye disorders	9	3	3	15
Total	9	3	3	15