ISRCTN39888829 https://doi.org/10.1186/ISRCTN39888829

Assessment of the effect of vitamin E supplementation on the ocular tear film

Submission date 29/09/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 01/10/2026	**Overall study status** Completed	
Last Edited 01/10/2026	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific, Public, Principal investigator

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Additional identifiers

Study information

Scientific Title
Potential benefits of short-term vitamin E supplementation for the ocular tear film: A randomized controlled trial

Acronym

VIT-E

Study objectives
Randomized controlled trial

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/11/2025, Institutional Review Board (IRB) at King Saud University (Health Sciences Colleges Researches on Human Subjects King Saud University, Riyadh, 11461, Saudi Arabia; +966 0114691529; fbashiri@ksu.edu.sa), ref: E-25-10201

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Basic science

Study type(s)

Health condition(s) or problem(s) studied
Impact of vitamin E on the ocular tear film

Interventions
Participants will receive oral vitamin E supplementation consisting of one JP Natural Vitamin E 400 IU softgel capsule (containing 268 mg natural alpha-tocopherol) taken once daily for three consecutive days. Baseline assessments will be conducted before supplementation and will include completion of the Standard Patient Evaluation of Eye Dryness (SPEED) questionnaire and tear film evaluations comprising non-invasive tear breakup time (NITBUT), tear meniscus height (TMH), and tear ferning (TF) tests. Participants will attend a follow-up visit 24 hours after the third vitamin E dose, during which the SPEED questionnaire and all tear film assessments will be repeated to evaluate changes in subjective symptoms of ocular dryness and objective tear film parameters. The control group will receive placebo capsules for comparison, and we will obtain measurements on days 1 and 4.

Intervention Type
Supplement

Primary outcome(s)
1. Ocular tear film parameters measured using the Standard Patient Evaluation of Eye Dryness (SPEED) questionnaire at day 1 and 4

2. Noninvasive tear breakup time (NITBUT) measured using the EasyTear View+ device at day 1 and 4

3. Tear meniscus height (TMH) measured using the EasyTear View+ device (mm) at day 1 and 4

4. Tear ferning (TF) measured using microscopic examination of dried tear samples using a five-point grading scale (Grade) at day 1 and 4

Key secondary outcome(s)

Completion date
30/03/2026

Eligibility

Key inclusion criteria
1. Healthy adults without eye diseases or disorders
2. Individuals who do not wear contact lenses
3. Have not undergone ocular surgery
4. Do not have high blood pressure

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
27 Years

Sex
All

Total final enrolment
64

Key exclusion criteria
Not meeting the key inclusion criteria

Date of first enrolment
06/01/2026

Date of final enrolment

26/03/2026

Locations

Countries of recruitment
Saudi Arabia

Sponsor information

Organisation
King Saud University

ROR
https://ror.org/02f81g417

Funder(s)

Funder type

Funder Name
College of Medicine, King Saud University

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Saudi Arabia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	30/09/2026	No	Yes
Protocol file	01/10/2026	No	No
Statistical Analysis Plan	01/10/2026	No	No