The influences of smartphone use on the status of the tear film and the ocular surface

Submission date	Recruitment status No longer recruiting	Prospectively registered		
22/06/2017		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
27/06/2017		[X] Results		
Last Edited	Condition category	Individual participant data		
11/07/2023	Eye Diseases			

Plain English summary of protocol

Background and study aims

Recently, with the increasing use of smartphones, some studies have reported eye health changes associated with smartphone use. As computer monitor work has an adverse effect on the tear film and the eye surface, smartphone use, which is similar to computer monitor work, is also expected to deteriorate the tear film and the eye surface. There has been no report on symptoms, clinical signs, and inflammation and oxidative stress in the eye surface related to smartphone use in healthy people. The aim of this study is to investigate the effects of smartphone use on eye strain, the tear film, and inflammation and oxidative stress in the eye surface in healthy volunteers.

Who can participate? Healthy volunteers over 20 years old

What does the study involve?

All measurements are carried out before and 1 and 4 hours after smartphone use. Eye symptoms, eye strain, the tear film, inflammation and oxidative stress in the eye surface are all assessed.

What are the possible benefits and risks of participating? Participants receive a small financial reward. There are no risks associated with this study.

Where is the study run from? Chonnam National University Hospital (South Korea)

When is the study starting and how long is it expected to run for? November 2016 to March 2017

Who is funding the study? Chonnam National University Hospital Biomedical Research Institute (South Korea)

Who is the main contact? Dr Kyung Chul Yoon

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

CNUH-2016-299

Study information

Scientific Title

The influences of smartphone use on ocular symptoms, status of the tear film, and oxidative stress in the ocular surface

Study objectives

As visual display terminal (VDT) work has an adverse effect on the tear film and the ocular surface, smartphone use, that is similar to VDT work, is also expected to deteriorate the tear film and the ocular surface.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of Chonnam National University Hospital, 18/11/2016, ref: CNUH-2016-299

Study design

Prospective observational clinical study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Tear film and the ocular surface

Interventions

All measurements were evaluated at baseline, 1 hour, and 4 hours after smartphone use. Subjective symptoms and asthenopia were evaluated by ocular surface disease index (OSDI), visual analogue scale (VAS), and computer vision syndrome (CVS) score. Fluorescein film break-up time (FBUT), non-invasive break up time (NIBUT), Schirmer score, keratoepitheliopathy (KEP), and tear meniscus height (TMH) were evaluated for status of the tear film. Levels of interleukin (IL)-1 β , IL-6, IL-17, tumor necrosis factor (TNF)- α , interferon (IFN)- γ , and macrophage inflammatory protein (MIP)-1 β were measured by multiplex immunobead assay in the tear film. Oxidative stress markers including hexanoyl lysine (HEL), 4-hydroxy-2-nonenal (4-HNE), malondialdehyde (MDA), and 8-oxo-2'-deoxyguanosine (8-OHdG) in the tear film were measured by ELISA. Reactive oxygen species (ROS) in the conjunctival epithelium were measured by 2',7'-dichlorodihydrofluorescein diacetate.

Intervention Type

Other

Primary outcome(s)

- 1. Ocular symptoms and asthenopia, evaluated by ocular surface disease index (OSDI), visual analogue scale (VAS), and computer vision syndrome (CVS) score before and after smartphone use
- 2. Status of the tear film, evaluated using fluorescein film break-up time (FBUT), non-invasive break up time (NIBUT), Schirmer score, keratoepitheliopathy (KEP), and tear meniscus height (TMH)

All outcomes were measured at baseline, 1 hour, and 4 hours after smartphone use

Key secondary outcome(s))

- 1. Levels of interleukin (IL)-1 β , IL-6, tumor necrosis factor (TNF)- α , interferon (IFN)- γ , interferon gamma-induced protein 10 (IP-10), and monokine induced by interferon- γ (MIG) measured in the tear film
- 2. Oxidative stress markers including hexanoyl lysine (HEL), 4-hydroxy-2-nonenal (4-HNE), malondialdehyde (MDA), and 8-oxo-2'-deoxyguanosine (8-OHdG) in the tear film measured by FIISA

All outcomes were measured at baseline, 1 hour, and 4 hours after smartphone use

Completion date

28/03/2017

Eligibility

Key inclusion criteria

- 1. Healthy adults without other ocular or systemic diseases which could affect ocular condition, or surgical history
- 2. Over 20 years old

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

80

Key exclusion criteria

- 1. Subjects who used any eye drops
- 2. Pregnant at the time of the study

Date of first enrolment

20/11/2016

Date of final enrolment

20/12/2016

Locations

Countries of recruitment

Korea, South

Study participating centre Chonnam National University Hospital

Korea, South 61469

Sponsor information

Organisation

Chonnam National University Hospital Biomedical Research Institute

ROR

https://ror.org/00f200z37

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Chonnam National University Hospital Biomedical Research Institute

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/10/2018	26/11/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<u>Protocol file</u>	version 1.2		11/07/2023	No	No