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

Submission date	Recruitment status	[_] Prospectively registered
22/06/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/06/2017	Completed	[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
Dr Kyung Chul Yoon

ORCID ID
http://orcid.org/0000-0001-8664-0639

Contact details
Department of Ophthalmology
Chonnam National University Medical School and Hospital
42 Jebong-ro
Dong-gu
Gwangju
Korea, South
61469

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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)-1β, IL-6, IL-17, tumor necrosis factor (TNF)-α, interferon (IFN)-γ, and macrophage inflammatory protein (MIP)-1β 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 measure
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

Secondary outcome measures
1. Levels of interleukin (IL)-1β, 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 ELISA
All outcomes were measured at baseline, 1 hour, and 4 hours after smartphone use

Overall study start date
18/11/2016

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

Age group
Adult

Sex
Both

Target number of participants
50

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

Sponsor details
Department of Ophthalmology
Chonnam National University Medical School and Hospital
42 Jebong-ro
Dong-gu
Gwangju
Korea, South
501757

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00f200z37

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chonnam National University Hospital Biomedical Research Institute

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
28/03/2018

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
Protocol file	version 1.2		11/07/2023	No	No