ISRCTN65345295 https://doi.org/10.1186/ISRCTN65345295

Comparing the effect of different eye drop instillation techniques

Submission date	Recruitment status	[_] Prospectively registered
02/08/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/08/2021	Completed	[_] Results
Last Edited	**Condition category**	[X] Individual participant data
09/08/2021	Eye Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Eye drops are commonly used in the treatment of eye conditions. They are used for the prevention or treatment of infective or inflammatory disorders, to prevent and decrease the complaints of dry eye, and for eye examinations.
Failure to properly administrate eye drops can prolong the condition, clinical outcomes can be negatively affected and may present a risk to the patients' vision.
The aim of this study is to investigate whether instillation of cyclopentolate eye drops to the corner of the eye and immediately opening the eyelid or opening of the lids in few seconds after instillation would make any difference on dilating the pupil and feeling of irritation while also comparing the traditional method with these two methods.

Who can participate?
Patients who require eye drops for eye examination

What does the study involve?
Participants were split into two groups. In both groups, one drop was administered in the traditional method into the right eye; in the left eye, the drop was instilled while the lids were closed. In the first group, the patient was asked to open his or her eye immediately, in the second group the patient was asked to open his or her eye after 10 seconds. The diameters of both pupils were measured before and after 40 minutes after the instillation of the eye drop. After the instillation, the feeling of irritation was evaluated with a visual analogue scale (VAS).

What are the possible benefits and risks of participating?
Patients might benefit from a more comfortable eye drop instillation experience, while the risk is the need for second eye drop instillation in the case the investigated method fails.

Where is the study run from?
University of Kocaeli (Turkey)

When is the study starting and how long is it expected to run for?
November 2017 to January 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Neriman Elibol, nerimanelibol@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2-2018

Study information

Scientific Title
Comparing efficiency of different eye drop instilling methods to traditional method within 10-70 age old patients.

Study objectives
There is no difference on efficiency between traditional and new eye drop instilling methods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/02/2018, Ethical Committe of Kocaeli University (Kocaeli Üniversitesi Umuttepe Yerleşkesi İzmit/Kocaeli; +902623037500; etikkurul@kocaeli.edu.tr), ref: KÜ GOKAEK 2018/32

Study design
Single center interventional non-randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Eye drop instillation method comparison

Interventions
Participants were randomly allocated to one of two groups. Participant patients arrive in a random time sequence (Patients arrive for periodic eye examination and asked to join the study prior to the examination and if volunteered patient consents are taken. Patients are not aware of which group they are participating in). The first patient was registered to group 1 and second to group 2 third to group 1 and so on until registrations are closed.

One drop of cyclopentolate was administered in the traditional method with the patient's head tilted back, the lower eyelid held and drop instilled into the inferior fornix in right eye. In the left eye the drop was instilled to the inner canthus while the lids were closed.

In the first group the patient was asked to open his or her eye immediately, in the second group the patient asked to open his or her eye after 10 seconds.

Intervention Type
Behavioural

Primary outcome(s)
Pupil size was measured under constant illumination with the Plusoptix A09 autorefractometer. The diameters of both pupils were measured before and after 40 minutes after the instillation of the eye drop. All drops were instilled by the same investigator while all pupil measurements were made by an ophthalmic specialist technician unaware of the study.

Key secondary outcome(s))
Feeling of irritation was evaluated with visual analogue scale (VAS), patients were asked how much irritation felt according to the scale 40 minutes after eye drop instillation

Completion date
30/01/2019

Eligibility

Key inclusion criteria
1. In need of pupil dilatation for ophthalmic examination.
2. Volunteering to participate in this study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
94

Key exclusion criteria
1. Patient requests to be excluded
2. Patients who use of ocular and systemic medications known to affect pupil size,
3. Patients who have pupil effecting disorders like pseudoexfoliation syndrome and pupillary membranes,
4. Patients with history of ocular surgery and trauma and cyclopentolate allergy

Date of first enrolment
01/02/2018

Date of final enrolment
01/11/2018

Locations

Countries of recruitment
Türkiye

Study participating centre
Dünyagöz İzmit Hastanesi
Kadıköy
Atatürk Blv. No:2
Kocaeli
Türkiye
41050

Sponsor information

Organisation
University of Kocaeli

ROR
https://ror.org/0411seq30

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Dataset		26/07/2021	03/08/2021	No	No