NTNU Norwegian University of Science and Technology Faculty of Medicine and Health Sciences.

Final Study Report

STUDY NO. 2019/1092

Version. 1.0, March 2023

Study Title: Optimizing disinfection before eye surgery.

REK Søknad:	2019/1092
EudraCT:	2019-001179-35

Investigational product:	Minims Povidone-Iodine 5% Eye Drops, Solution, Bausch and Lomb
Study design:	Randomized controlled trial
Study initiation date:	01.01.2020
Study completion date:	30.04.2020
Study performed at:	St. Olavs Hospital, Trondheim University Hospital, Trondheim, Norway

Principal Investigator:	Dordi Austeng Dept. of Ophthalmology, St. Olavs Hospital, Faculty of Medicine and Health Sciences, NTNU, Trondheim, Norway
Sponsor:	Marit Fagerli Head of Department, Dept. of Ear-nose-throat, Maxillofacial surgery and Ophthalmology, St. Olavs Hospital, Trondheim, Norway

FINAL STUDY REPORT

Study No: 2019/1092

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PRINCIPAL INVESTIGATOR'S SIGNATURE

STUDY TITLE: Optimizing disinfection before eye surgery

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

This study was conducted according to the principles of Good Clinical Practices.

Date	Signature
14.03.2023	Dordi Austeng

Principal Investigator
Dordi Austeng, MD. Ph.D. Dept. Ophthalmology, St. Olavs Hospital. NTNU, Trondheim, Norway

SYNOPSIS

Study number	2019/1092
Title	Optimizing disinfection before eye surgery
EudraCT number	2019-001179-35
Name of Product	Betadine
Name of Active Ingredient	Povidone-Iodine 5%
Indication	Disinfection before eye surgery at Dept of Ophthalmology, St. Olavs Hospital, Trondheim University Hospital
Name of Sponsor	Marit Fagerli, Head of Department, Dept. Ear-nose-throat and Ophthalmology, St. Olavs Hospital, Trondheim University Hospital
Investigator	Dordi Austeng, MD Ph.D.
Study centre	St Olavs Hospital, Trondheim, Norway
Publications	Not published.
Period of Trial	01.01.2020 – 30.04.2020
Objectives	Testing the antiseptic effect of two concentration of Povidone-Iodine (PI)
Methodology	Randomized controlled study in which the eyes of the participants were tested with different concentrations of disinfectant. In this way, the participants acted as their own control.
Number of subjects	150
Main criteria for inclusion	Patients referred to intravitreal injections, aged 50 years or older, with adequate cognitive state to understand the given information.
Investigational Medicinal Product	Minims Povidone-Iodine 5% Eye Drops, Solution, Bausch and Lomb
Duration of treatment	Patients were given a pledget soaked in Povidone-Iodine 0.3% in fornix inferior in one eye for 20 minutes (the intervention). In the other eye they were given Povidone- Iodine 5% eye drops (todays standard treatment)
Criteria for evaluation Efficacy	The change in the number of conjunctival bacteria obtained from conjunctival samples taken before and after disinfection of the eyes.
Safety	Cases were reported individually.
Statistical methods	Paired test for categorical data. Analysis for sample size showed that we should include 150 patients and take samples from both eyes of all participants to be able to reject the null hypothesis with 95% probability. With this study design, we would be able to compare the number of bacteria before treatment against the amount after treatment in the two eyes and assess whether there was any statistically significant difference in the bacteria-reducing effect between the two treatment options.
Procedures	Paired pre – and post disinfection conjunctival samples from 150 participants were obtained the day they came to intravitreal injection. One eye was given a pledget soaked in Povidone-Iodine 0.3% for 20 minutes. The other eye was given Povidone- Iodine 5% eye drops for 2 minutes. The eyes were randomized to the

	two treatments.
Safety results	No clinically significant adverse event was observed.
Conclusions	Due to the low proportion of conjunctival samples with bacterial growth, we were unable to draw any conclusions from this study. We did an interim analysis after 50 and 100 sampling and checked all the steps in the sampling procedure and found no deviation from the standard procedure. The reason for the lower proportion of samples with growth could possibly be related to the patient group, as these are patients who have received repeated treatments with povidone-Iodine over several years.
Date of Report	14.03.2023

LIST OF ABBREVIATIONS

Abbreviation or special term	**Explanation**
AE	Adverse Event
CI	95% confidence interval
AE	Adverse Event
GCP	Good Clinical Practice
IMP	Investigational Medicinal Product
NTNU	Norwegian University of Science and Technology
OSS	Ocular Surface Score
PI	Povidone- Iodine
RCT	Randomized Controlled Trial
SAE	Serious Adverse Event
VNRS	Verbal Numerical Rating Scale

TABLE OF CONTENTS

1. ETHICS

1.1 INDEPENDENT ETHICS COMITEE OR INSTITUTIONAL REVIEW BOARD

The study was approved by The Norwegian Medicines Agency (EudraCT number: 2019-001179-35) and the Regional Committees for Medical and Health Research Ethics (2019/1092) before inclusion of participants.

1.2 ETHICAL CONDUCTION OF THE STUDY

The study was conducted according to the principles of the Declaration of Helsinki and was consistent with ICH-GCP. Registration and storage of participant data were carried out in accordance with national privacy laws and regulations. Participant's medical records have been accessed to evaluate inclusion and exclusion criteria. The subjects were identified by participant number and initials. The identifier list was in a safe and only study personnel had access. The identifier list is now deleted. The participants were insured during the trial.

1.3 PARTICIPANT INFORMATION AND CONSENT

The Regional Committee of Medical and Health Research Ethics approved the participant information and the informed consent form along with the approval of the study. Participants were recruited among patient remitted to intravitreal injections at Department of Ophthalmology, St. Olavs Hospital. They were given information, both written and verbal at the department at different occasions before they consented to participation.

Study personnel have given the subjects full and adequate verbal and written information about the nature, purpose, possible risk and benefit of the study. They have been informed about the strict confidentiality of their participant data. It has been emphasized that the participation is voluntary and that they without consequence may terminate their participation in the study at any time.

Documented informed consent was obtained for all participants included in the study before they were screened for inclusion. The signed and dated participant consents were filed along the duration of the study. A copy of the information about the study was also given to the participants. A sample patient consent form is provided in appendix 10.1.

2. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

Sponsor	Marit Fagerli, Head of Department, Dept. of Ear-nose-throat, Maxillofacial surgery and Ophthalmology, St. Olavs Hospital, Trondheim, Norway
Principal Investigator	Dordi Austeng, MD, PhD Department of Neuromedicine and Movement Science, Norwegian University of Science and Technology, Trondheim, Norway Department of Ophthalmology, St. Olavs Hospital, Trondheim University Hospital, Trondheim, Norway
Laboratory facilities	Department of Microbiology, St. Olavs Hospital, Trondheim University Hospital, Trondheim, Norway

3. INTRODUCTION – BACKGROUND AND RATIONALE

Endophthalmitis is a feared postoperative complication to surgery with an incidence proportion found to be approximately 0.05. Although rare, prevention of this bacterial induced complication is of great importance since it may lead to poor visual outcome even with appropriate treatment. Bacterial contamination to the eye originates from the eyelid, periorbital skin and conjunctiva, but the conjunctiva is assumed to be the primary source to the commensal bacteria that increases the risk of developing endophthalmitis. A reduction in preoperative conjunctival bacterial load is thus of outmost importance to reduce the risk of this severe complication.

Povidone-Iodine (PI) is the most used antiseptic substance since it was introduced in the 1950s and has been applied within ocular surgery since the 1990s. PI is highly effective against a wide spectrum of microbes, there is no observed resistance, and it does not seem to influence healing of wounds. The tissue toxicity of PI depends on the concentration, and a higher concentration (>1%) seems to damage the corneal epithelial cells (Jiang J. et al. The toxic effect of different concentrations of povidone iodine on the rabbit´s cornea. Cutan Ocul Toxicol. 2009;28:119–24). In humans, a concentration level at 5% PI has most often been used when disinfecting the eyelid, conjunctiva and eye before ocular surgery. In vitro studies have shown bactericidal effect of even lower concentrations of PI and results from another clinical study, suggested a substantial bactericidal effect of repeated irrigation of low-concentration PI (0.25%) during cataract surgery, reducing anterior chamber contamination (Shimada H. et al. Reduction of anterior chamber contamination rate after cataract surgery by intraoperative surface irrigation with 0,25% povidone-iodine. Am. J Ophthalmol. 2011;151:11-17). We have earlier shown that preoperative treatment with long-term, low-concentration PI applied via a depot device in fornix inferior reduced the number of bacteria in the conjunctiva in most study participants (Wass S. et al. Antiseptic effect of low concentration povidone-iodine applied with a depot device in the conjunctiva before cataract surgery. Eye 2018;32:1900-1907). However, it is not known whether the effect is as good as standard treatment (5% PI).

4. STUDY OBJECTIVES

The primary aim of this study was to test the antiseptic effect of long-term low-concentration (0.3%) PI against standard 5% treatment with PI in the conjunctiva.
A secondary aim was to examine the level of pain and the corneal epithelial damage caused by the two PI concentrations (0.3% and 5%, respectively).

5. INVESTIGATIONAL PLAN

5.1 OVERALL STUDY DESIGN AND PLAN-DESCRIPTION

A randomized controlled trial in which the eyes of the participants were tested with different concentrations of disinfectant. In this way, the participants acted as their own control. The study was open label (no blinding).
Participants referred to intravitreal injections at the Department of Ophthalmology, St. Olavs Hospital, Trondheim University Hospital, during 01.01.20 – 30.04.20, were invited to participate in the study. Potential subjects were screened for inclusion by interview. One hundred and fifty consenting subjects fulfilling the inclusion/exclusion criteria were included.
The participants' eyes were randomized to receive a pledget of 0.3% Povidone-Iodine (PI) placed in the fornix inferior in one eye for 20 minutes and one single drop of 5% PI in the other eye. A conjunctival sample was obtained from the fornix inferior of both eyes before and after treatment. The analysis of the bacterial samples was performed at the laboratories at the Dept. of Medical Microbiology.
Fifty of the participants were asked to rate their pain in each eye on a scale of 0 (no pain) to 10 (worst thinkable pain) using a Verbal Numerical Rating Scale (VNRS). They rated their pain right after both eyes were disinfected (T1) and after an hour, when the local anesthetic had worn off (T2). Finally, both eyes were instilled with fluorescein dye and examined in a slit lamp. The corneal epithelial damage was evaluated using a modified quantitative Ocular Surface Score (OSS).

5.2 DISCUSSION OF STUDY DESIGN, INCLUDING THE CHOICE OF CONTROL GROUP

The main aim of the study was to test the antiseptic effect of long-term low-concentration (0.3%) PI on the growth of bacteria in the conjunctiva of one eye, compared to standard treatment of 5% PI eyedrops given in the other eye of the same patient. The secondary aims were to examine whether the disinfection methods caused the same amount of discomfort for the patients and the same damage to the corneal epithelium.
The study was not blinded. Neither the study staff nor the participants were masked for the two study groups. We discussed this when we planned the study, but found no solution based on the resources we had available. With an extra room, we could have managed to blind the study staff. And by placing a pledget in both eyes, one with PI (which we used in the study) and one without (a placebo), we could have managed to blind the participants.
The study population, elderly remitted to intravitreal injections, was chosen as this is a large population that regularly come for treatment at the department. It would be easy to reach out and to recruit participants to the study.

5.3 SELECTION OF STUDY POPULATION

Participants referred to intravitreal injection at the Department of Ophthalmology, St. Olavs Hospital, Trondheim University Hospital, during 01.01.20- 30.04.20, were invited to participate in the study. Information about the study was given both oral and written. Posters were put up at the injection clinic for the patients to read and the names of the interested patients were noted. Patients who wanted to

participate and fulfilled the inclusion criteria, were called at least 48 hours before their scheduled time. This allowed the participants to evaluate their decision.

5.3.1 INCLUSION CRITERIA

Age 50 years or older.
Adequate cognitive state to understand the given information.

5.3.2 EXLUSION CRITERIA

Participants were excluded from the study if they met any of the following criteria:

- Allergy for eye drops.
- Use of any kind of eye drops/ointment last 4 weeks.
- Use of systemic antibiotics or corticosteroids last 4 weeks.
- Ongoing ocular or orbital infection or inflammation
- Patients with diabetes
- Patients who must wear contact lenses.

5.3.3 REMOVAL OF PATIENTS FROM THERAPY OR ASSESSMENT

Patients with red eyes, infections or who on the study day withdraw their consent, will be removed. We did not experience any of this in the present study.

5.4. TREATMENTS

Every participant was exposed to the same treatment; a pledget soaked in 0.3% PI placed in fornix inferior in one eye for 20 minutes and standard 5% PI eye drops in the other eye. The participants' eyes were randomized so that an equal number of right and an equal number of left eyes received the same treatment.

5.4.1 BLINDING

There was no blinding, but we did not tell the patients which treatment they were given in each eye. The most observant would note that one eye received a pledget while the other received an eye drop.

5.5 EFFICACY AND SAFETY VARIABLES

5.5.1 EFFICACY AND SAFETY MEASUREMENTS ASSESSED

Efficacy

There was no assessment of efficacy i.e. clinical response to the treatment. The following parameters were evaluated:

- Number of bacterial colonies in conjunctiva in patients who voluntarily participated in the study before receiving treatment with intravitreal injections at St. Olavs Hospital.
- Pain experienced in each eye right after both eyes were disinfected (T1) and after an hour, when the local anesthetic had worn off (T2).
- Corneal epithelial damage in each eye after treatment.

Safety

The risks to human subjects were minimal in this study. Povidone-Iodine is a well-known, well-tolerated drug with an excellent safety profile over many decades of use. No significant side effects or adverse reactions occurred in the study.

Adverse event registration

The principal investigator was responsible for documentation of events meeting the criteria and definition of an adverse event (AE) or serious adverse event (SAE). Each participant was instructed to contact the investigator immediately should they manifest any signs or symptoms they perceive as serious. Information was also be obtained by questioning during the study sessions. Subjective complaints, abnormal physical findings or deviation from expected were to be recorded.

Criteria for discontinuation of participants or the trial

Participants could be discontinued from study treatment and assessments at any time. Specific reasons for discontinuing a patient for this study were:

- Voluntary discontinuation by the subject who is at any time free to discontinue his/her participation in the study, without prejudice to further treatment.
- Safety reason as judged by the Principal Investigator
- Non-compliance to protocol as judged by the Principal Investigator
- Incorrect enrollment i.e., the subject does not meet the required inclusion/exclusion criteria for the study

5.5.2 PRIMARY EFFICACY VARIABLE

The difference between the bacteria-reducing effect of the two disinfection methods was the primary endpoint of this study. The laboratory method is described and used in the earlier study from the research group (Wass et al.). There was no assessment of efficacy, i.e. clinical response to the treatment.

5.6 DATA QUALITY ASSURANCE

The same study coworkers were taking all the samples from the participants eyes, asked the patients the questions about pain during and after the disinfection of the eyes and performed the examination in the slit-lamp.

At the Dept. of Medical Microbiology, two co-workers were plating the samples to the agar plates and made the analyzes, counting the number of bacteria per milliliter according to standard procedure. The results were stored in the patient records. After the results were digitally available in the patient records, they were noted in the study excel-file.

5.7 STATISTICAL METHODS PLANNED IN THE PROTOCOL AND DETERMINATION OF SAMPLE SIZE

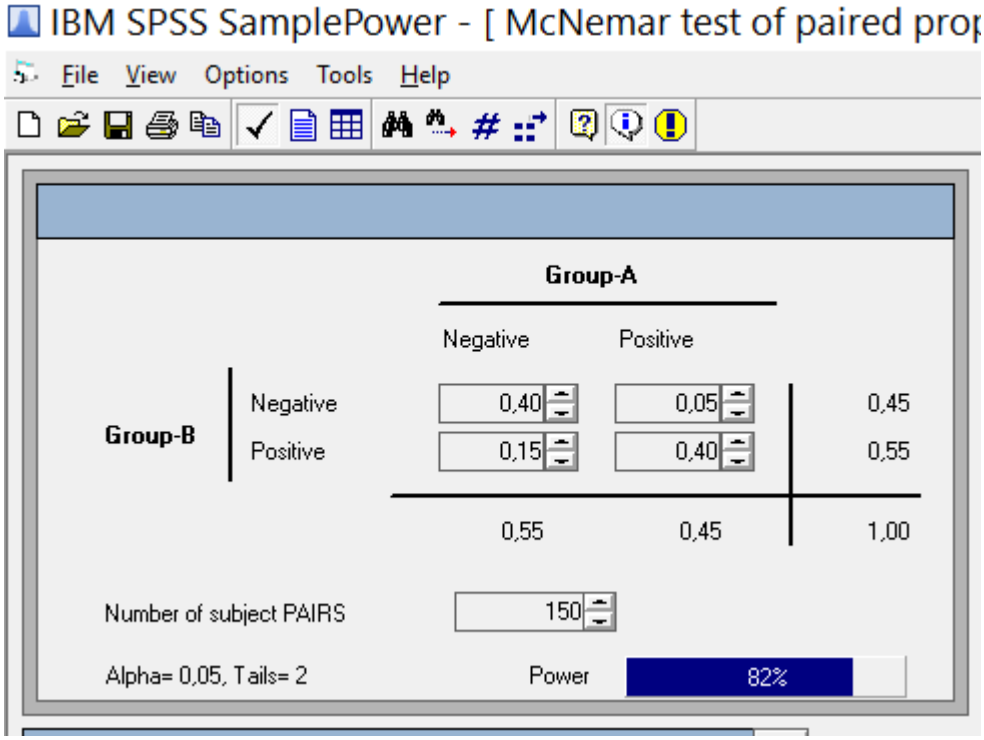
5.7.1 STATISTICAL AND ANALYTICAL PLANS

Testing both eyes of a patients, we have matched pairs of data. We then must use methods that consider dependencies within the pairs. In this study we would analyze data on bacterial counts before and after

treatment of the right and left eye respectively. Mc Nemar's test is then recommended.
For the secondary analyses, pain score and corneal epithelium evaluation, a non-parametric test was planned as data would probably not be normally distributed, e.g., Wilcoxon Signed Rank Test. The difference between the right and the left eye before and after intervention would be analyzed.

5.7.2 DETERMINATION OF SAMPLE SIZE

In cooperation with a statistician at Department of Public Health and Nursing, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology, Trondheim, Norway, we decided to use methods for analysis of paired proportions. From calculations using McNemars test of paired proportions, we needed to include 150 patients to be able to discard the null-hypothesis: a low-concentration of PI will give a significant reduction in bacterial colonies around the eye, compared to standard PI 5%.



Estimation of sample size needed for power >80% and significance level <0.05.
Group A = treatment 1 (in one of the eyes)
Group B = treatment 2 (in the other eye)
Neg-neg: no change (no effect of the treatment)
Pos-pos: effect of both treatments
Pos-neg (effect of treatment B, not A), treatment B is best.
Neg-pos: treatment A is best.

We did a separate estimation of the sample size for the secondary outcomes, this as scoring the pain and examination with the slit lamp are more time consuming. The estimated sample size needed to detect a difference between the two groups of 1 point on a pain scale from 0-10 was 33 participants. Standard deviation was anticipated to be 2, statistically significance 0.05 and power 0.8. Based on these estimates we decided to divide our participants into two groups; for the first 50 participants pain, corneal epitheliopathy and antibacterial effect were all evaluated. Only the antibacterial effect was assessed on the remaining 100 participants.

5.8 CHANGES IN THE CONDUCT OF THE STUDY OR PLANNED ANALYSES

No changes were made to the plan.

6. STUDY PARTICIPANTS

6.1 DISPOSITION OF PARTICIPANTS

Informed consent for participation was ascertained from 150 participants. All these had conjunctival samples taken before and after treatment. The first 50 participants were in addition asked about pain during and after the treatment and they were examined in the slit lamp to evaluate their corneal epithelium after treatment.

6.2 PROTOCOL DEVIATIONS

No protocol deviations.

7. EFFICACY EVALUATION

The efficacy was measured in number of bacterial colonies in conjunctival samples taken before and after treatment with Povidone-Iodine.

7.1 DATA SETS ANALYZED

Primary outcome: Bacterial count in conjunctival samples

All 150 participants received treatment according to the protocol and of these 40% had growth of bacteria in conjunctival samples taken from one eye before treatment. Only 20% had growth of bacteria from both eyes before treatment. The proportion of positive bacterial samples was less than expected. Interim analyses were performed after sampling from 50 and 100 participants and all steps in the procedure were reviewed, but no reason for the lower bacteria detection was found. As we did not have 150 paired samples with bacterial growth, we had to refrain from further analyses of the dataset.

Secondary outcomes

A total of 100 eyes of 50 subjects were included in the analyses of the secondary outcomes. The mean age of this group was 78, ranging from 50-95. 28 were female (56%), 22 were male (44%).

Pain score

There was a significant higher mean pain score before treatment in eyes receiving 5% PI compared to eyes receiving 0.3% PI (1.58 vs 0.48, $p < 0.001$). The difference in mean pain score after treatment was also significant (1.64 vs 0.44, $p < 0.001$).

Corneal epithelium evaluation

Eyes receiving 5% PI had a significant higher mean staining score than eyes receiving 0.3% PI (4.98 vs. 1.6, $p < 0.001$), indicating a higher degree of corneal epithelial damage.

7.2 DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

Not applicable.

7.3 MEASUREMENTS OF TREATMENT COMPLIANCE

All treatments were conducted under supervision of study personnel. Compliance was therefore not considered to be an issue.

7.4. EFFICACY RESULTS

7.4.1 ANALYSES OF EFFICACY

The proportion of positive bacteria samples was less than expected and we had to refrain from further analyses of the data set as explained in section 7.1. above.

7.4.2 STATISTICAL/ANALYTICAL ISSUES

The statistical analyses were not carried out according to plan, as explained in section 7.1.
Interim analysis was performed after 50 and 100 participants, as explained in section 7.1.

8. SAFETY EVALUATION

All subjects that entered the study and received treatment were along the study monitored by nurse and ophthalmologist for any possible side effects from the treatment or from the data collecting procedures.

8.1 EXTENT OF EXPOSURE

The participants have been exposed to the marketed product Minims® Povidone Iodine 5% w/v Eye Drops, Solution, for this study diluted to a concentration of 0.3%. 150 subjects were exposed to the product. All subjects were included in the safety analysis.

8.2 ADVERSE EVENTS (AES)

8.2.1 BRIEF SUMMARY OF ADVERSE EVENTS

The most serious adverse reaction that occur with Minims® Povidone Iodine 5% w/v Eye Drops, Solution is hypersensitivity reaction. Rare side effects affecting the eye is conjunctival hyperemia and superficial punctuate keratitis.

8.2.2 DISPLAY OF ADVERSE EVENTS

No adverse events were reported.

8.2.3 ANALYSIS OF ADVERSE EVENTS

No adverse events were reported.

8.3 DEATHS, OTHER SERIOUS ADVERSE EVENTS, AND OTHER SIGNIFICANT ADVERSE EVENTS

There have been no deaths, no serious adverse event, and no other significant adverse event.

8.4 CLINICAL LABORATORY EVALUATION

Repeated measurements of conjunctival samples were part of the study and were not re-evaluated during the study.

8.5 VITAL SIGNS, PHYSICAL FINDINGS, AND OTHER OBSERVATIONS RELATED TO SAFETY

There were no clinically relevant changes apparent in the vital signs observed.

8.6 SAFETY CONCLUSIONS

Preoperative treatment with PI applied via a depot device in fornix inferior (0.3%) or as eye drops (5%) was well tolerated by the participants in the study.

9. DISCUSSION AND OVERALL CONCLUSIONS

The main aim of the study, testing the antiseptic effect of long-term low-concentration PI (0.3%) in conjunctiva compared to standard treatment of PI (5%) eyedrops, was not achieved. This as the proportion of samples with bacterial growth before treatment, was less than anticipated. The reason for this is not known. We thought that the cause could lie with the sampler, we therefore checked the sampling technique, and it was the same as in the previous study by the research group. We also changed the sampler, but this did not improve the proportion of samples with growth. The reason may lie in the patient group. The conjunctiva, the mucous membranes of the eye, could possibly be different in the patient group we tested compared to the healthy volunteers in the previous study from the research group (Wass S. et al. Antiseptic effect of low concentration povidone-iodine applied with a depot device in the conjunctiva before cataract surgery. Eye 2018;32:1900-1907). The patients have undergone several treatments where the conjunctiva was disinfected with iodine. The conjunctiva may have changed in this population receiving repeated treatments. The mucous membranes also change with age, but the average age did not differ much between this and the previous study (77 versus 75 years).

The secondary aims were to examine whether the disinfection methods caused the same amount of discomfort for the patients and the same irritation of the corneal epithelium. PI is well known to cause pain and discomfort among patients, but only a few studies have investigated this. As far as we know, no former studies have assessed the subjective experience of different concentrations of PI. The present study therefore provides a new insight into the relationship between the concentration of PI and level of pain. Our findings indicate that a higher concentration of PI causes more pain than a lower concentration. This seems logical as PI is known to be cytotoxic and a former study showed that increased concentration of PI lead to increased corneal epitheliopathy (Jiang J. et al. The toxic effect of different concentrations of povidone iodine on the rabbit´s cornea. Cutan Ocul Toxicol. 2009;28:119–24). The present study further confirms this as eyes receiving PI 5% had more corneal epithelial irritation than eyes treated with PI (0.3%).

10. APPENDIX.

10.1 PATIENT CONSENT FORM

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET

«Optimalisering av desinfeksjon ved øye operasjoner»

Dette er et spørsmål til deg om å delta i et forskningsprosjekt for å finne ut hvilken konsentrasjon av jod som mest effektivt hindrer vekst av bakterier før øyeoperasjoner. Vi har spurt deg om å delta i dette prosjektet fordi du får behandlinger med injeksjoner i øyet, og det er slik vi har identifisert deg.

Ved øyeavdelingen vasker vi huden og drypper øyet med jod 5% før operasjoner og denne standard behandlingen er ikke endret. Studien vi spør om du vil delta i vil foregå før du får standard behandling.

HVA INNEBÆRER PROSJEKTET?

Hvis du takker ja til deltakelse i studien vil vi ta en bakterieprøve av tårevæsken og gi deg jod 5% på det ene øyet og en svakere jodløsning, 0,3% på det andre øyet. Behandlingen tar 20 minutter. Deretter tas en ny bakterieprøve av tårevæsken. Etter avsluttet behandling blir du bedt om å svare på et spørsmål om hvordan øyet oppleves etter behandlingen.

Etter at du har deltatt i studien, får du standard behandling som hvis du ikke hadde deltatt i studien. Således medfører studien att du får en ekstra desinfiserende behandling før injeksjon. Vi estimerer totalt tidsbruk til ca 1 time.

I prosjektet vil vi innhente og registrere følgende opplysninger om deg: Vi kommer ta prøve av tårevæsken og telle bakterier fra den. Vi kommer deretter til å be deg svare på hvordan du opplevde behandlingen. Vi kommer ikke til å lagre studiedata i journalen din.

MULIGE FORDELER OG ULEMPER

Fordeler ved å delta i studien: Det innebærer ingen spesielle fordeler for deg å delta i denne studien.

Ulemper ved å delta i studien: Det vil bli tatt to prøver fra hvert øye og gitt jod. Prøvene tas med en vattpinne og kan medføre et kortvarig mildt ubehag. Studien innebærer at du får en ekstra desinfiserende behandling i øynene før injeksjon. Du kan ikke bruke kontaktlinser den dagen prøvene tas.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE SITT SAMTYKKE

Det er frivillig å delta i studien. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dette vil ikke få konsekvenser for din videre behandling. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

HVA SKJER MED OPPLYSNINGENE OM DEG?

Opplysningene som registreres om deg skal kun brukes slik som beskrevet i hensikten med prosjektet. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene.

Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun prosjektleder og prosjektmedarbeidere som har tilgang til denne listen. Opplysningene om deg vil bli anonymisert eller slettet senest tre år etter prosjektslutt.

Representanter fra klinikkledelsen ved St. Olavs hospital, Statens legemiddelverk og kontrollmyndigheter i inn- og utland kan få utlevert studieopplysninger og gis innsyn i relevante deler av din journal. Formålet er å kontrollere at studieopplysningene stemmer overens med tilsvarende opplysninger i din journal. Alle som får innsyn i informasjon om deg har taushetsplikt.

DELING AV DATA OG OVERFØRINGER TIL UTLANDET

Ved å delta i prosjektet, samtykker du også til at opplysninger om bakterieantall, effekt av gitt medikament og svar på hvordan du opplevde behandlingen overføres til utlandet som ledd i forskningssamarbeid og publisering. Dette kan være land med lover som ikke tilfredsstiller europeisk personvernlovgivning. Prosjektleder vil sikre at dine opplysninger blir ivaretatt på en trygg måte.

Koden som knytter deg til dine personidentifiserbare opplysninger vil ikke bli utlevert.

HVA SKJER MED PRØVER SOM BLIR TATT AV DEG?

Prøvene som tas av deg lagres i to måneder på reservert plass på Avdeling for medisinsk mikrobiologi St. Olavs Hospital under ansvar av dr. Olaf Strømme.

FORSIKRING

Du er forsikret gjennom Lov om produktansvar i Legemiddelforsikringen.

GODKJENNING

Regional komité for medisinsk og helsefaglig forskningsetikk har vurdert prosjektet og gitt forhåndsgodkjenning (REK vest 2019/1092). Både NTNU og St. Olavs hospital er forskningsansvarlige for studien.

Etter ny personopplysningslov har dataansvarlig Jorunn Helbostad (instituttleder, INB, NTNU) og Dordi Austeng (prosjektleder) et selvstendig ansvar for å sikre at behandlingen av dine opplysninger har et lovlig grunnlag. Dette prosjektet har rettslig grunnlag i EUs personvernforordning artikkel 6a og artikkel 9 nr. 2 og ditt samtykke. Du har rett til å klage på behandlingen av dine opplysninger til Datatilsynet.

KONTAKTOPPLYSNINGER

Dersom du har spørsmål til prosjektet kan du ta kontakt med Dordi Austeng, telefon 72 57 53 00
Telefontid 08.00-11.00. Callback etter kl. 11.00. E-post: dordi.austeng@stolav.no
Personvernombud ved institusjonen kan nås på: personvernombudet@stolav.no
Dersom sensitive opplysninger, kontakte personvernombudet på adresse: St. Olavs Hospital HF, Personvernombudet, Postboks 3250 Torgården, 7006 Trondheim

JEG SAMTYKKER TIL Å DELTA I PROSJEKTET OG TIL AT MINE PERSONOPPLYSNINGER OG MITT BIOLOGISKE MATERIALE BRUKES SLIK DET ER BESKREVET

Sted og dato

Deltakers signatur