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Nationwide survey of prosthetic eye users

Submission date	Recruitment status	[X] Prospectively registered
22/03/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/07/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/09/2021	Eye Diseases	

Plain English summary of protocol

Background and study aims
Patients who wear an ocular prosthesis (also known as an artificial eye) often suffer with dry eye symptoms. Up to 90% will also complain of socket discharge, many on a daily basis. No literature exists on their quality of life post eye loss or adapting to monocular vision. There is little data in the field of artificial eye care. A nationwide study could provide the data on current artificial eye patients, ranging from reason for eye loss through to experience on wearing their ocular prosthesis and finally any change in quality of life following eye loss. The aim of this study is to compare patient comfort and satisfaction existing ocular prosthesis users and collate data on prosthetic eye users.

Who can participate?
Adults aged 18 and older who wear a prosthetic eye attending any Eye Service.

What does the study involve?
Participants are asked to fill out an anonymous questionnaire while waiting for an outpatient appointment. The questionnaire will ask about their experience of their ocular prosthesis and related care. There is no follow up required.

What are the possible benefits and risks of participating?
There are no benefits or risks with participating.

Where is the study run from?
This study is being run by the Queen Victoria Hospital (UK) and takes place in any Eye service or National Health Service Maxillofacial Prosthetic Departments (UK).

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

Who is funding the study?
1. Queen Victoria Hospital (UK)
2. Institute of Maxillofacial Prosthetists and Technologists (UK)

Who is the main contact?
Dr Emma Worrell

Contact information

Type(s)
Scientific

Contact name
Dr Emma Worrell

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Additional identifiers

EudraCT/CTIS number

IRAS number
218611

ClinicalTrials.gov number

Secondary identifying numbers
IRAS No 218611

Study information

Scientific Title
A nationwide survey of prosthetic eye users: A collaborative study with all NHS ocular prosthetic service providers

Study objectives
The aim of this study is to compare patient comfort and satisfaction existing ocular prosthesis users and collate data on prosthetic eye users.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland Research Ethics Service, 21/02/2017, ref: NRES 17/ES/0010

Study design

Observational cross sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Artificial eye users

Interventions
Participants are given anonymous questionnaires to fill out while they are waiting for their outpatient appointments. The questionniares are available to patients in all eye services (Ocular /Corneoplastic/Ophthalmology) or National Health Service Maxillofacial Prosthetic Departments. The questionnaires will ask about their ocular prosthesis and related care. The study runs until May 2019 and there is no follow up required. Questionnaires are collected by the research team and entered on study databases.

Intervention Type
Device

Primary outcome measure
1. Incidence of anophthalmia is analysed using participant questionnaires
2. Length of prosthetic eye use is analysed using a participant questionnaires
3. Length of ocular wear is analysed using participant questionnaires
4. Age of prosthesis is analysed using participant questionnaires
5. Cleaning regime is analysed using participant questionnaires
6. Lubricant use is analysed using participant questionnaires
7. Inflammation is analysed using participant questionnaires
8. Comfort is analysed using participant questionnaires
9. Discharge is analysed using participant questionnaires
10. Quality of life is analysed using participant questionnaires

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
01/04/2017

Completion date
01/08/2019

Eligibility

Key inclusion criteria
1. Patients wearing a prosthetic eye or cosmetic shell, attending any Eye Service (Ocular /Corneoplastic/Ophthalmology) or National Health Service Maxillofacial Prosthetic Departments.
2. Over 18 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500 as a minimum sample size

Total final enrolment
1185

Key exclusion criteria
1. Patients under the age of 18 years of age
2. Patients not wearing a prosthetic eye (e.g. purely an eye conformer)
3. Patients who are unable to give their own consent, under Mental Capacity Act (MCA) 2005

Date of first enrolment
07/07/2017

Date of final enrolment
31/05/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Victoria Hospital
Holtye Road
East Grinstead

RH19 3DZ
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Sponsor information

Organisation
Queen Victoria Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ywpxj09

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Queen Victoria Hospital

Funder Name
Institute of Maxillofacial Prosthetists and Technologists

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

To write a nationally agreed cleaning protocol or best practice document. The goal is to produce a simple and readily available leaflet for the clinical environment and a downloadable pdf available on each organisation's website. This study hopes to improve patient's artificial eye tolerance and reduce deposit build up, reduce symptoms of discharge, ultimately improving the patient experience. This evidence based research will inform and prepare any future new patients; whether through NHS clinics, GP surgeries or affiliated ocular organisations. In addition this research could be used as an update to the most commonly suggested book for adapting to monocular vision: 'A singular view' The art of seeing with one eye by Frank B. Brady, first published in 1972.

Intention to publish date

01/08/2020

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	comfort and satisfaction results	26/10/2020	23/09/2021	Yes	No
Results article	demographics, comfort and satisfaction results	05/09/2020	23/09/2021	Yes	No
Results article	maintenance, management and quality of life results	04/01/2021	23/09/2021	Yes	No
Results article	visual function and quality of life results	01/03/2021	23/09/2021	Yes	No
HRA research summary			28/06/2023	No	No