A review of contact lens type and contact lens replacement in children with aphakia

A Data Management Plan created using DMPonline

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Template: UMC Utrecht DMP

Project abstract:

Contact lenses are a treatment for visual rehabilitation in paediatric aphakia. Several contact lens types and designs are used. For the first lens choice a protocol is followed based on lens fit and the oxygen permeability. The lenses are replaced on a three-monthly basis or at an earlier interval when needed. Several studies have assessed the success of specific contact lens types. No study compares the success of different lens types for aphakia or at specific ages. The aim of this retrospective case review is to assess the suitability and success of different lens types in different stages of infant aphakia correction, based on average duration of wear per lens, average time of lens wear and reasons to cease lens wear.

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1. General features

1.1. Please fill in the table below. When not applicable (yet), please fill in N/A.

DMP template version	29 (don't change)
ABR number *(only for human-related research)*	N/A
METC number *(only for human-related research)*	19-744
DEC number *(only for animal-related research)*	N/A
Acronym/short study title	CLAR/Contact lens wear in aphakic children
Name Research Folder	19-744_CLAR
Name Division	Heelkundige Specialismen
Name Department	Oogheelkunde
Partner Organization	Visser Contactlenzen Praktijk
Start date study	01/11/2019
Planned end date study	01/06/2020
Name of datamanager consulted*	D. Steins
Check date by datamanager	30-03-2021

1.2 Select the specifics that are applicable for your research.

- Multicenter study
- Retrospective study
- Non-WMO
- Observational study

Multicenter study: Vumc, UMC Utrecht

2. Data Collection

2.1 Give a short description of the research data.

For this multicenter retrospective study, we aim to explore contact lens characteristics (e.g. lens design, replacement time, etc.) in children (aged <9 years) with aphakia treated between 1 January 2008 and 1 January 2018, within the Visser Contact Lens Practice.

Data will be manually extracted from the paper and electronic health records (EHRs, HiX) and Navision 2015 (software program endorsed by Visser Contact lenzen) by members of the research team. After which, the members of research team will enter this data into a web-based data management application (the UMCU endorsed system Castor EDC).

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	93	EPD (HiX)	Castor	Quantitative	.sav	0-10 GB
Human	93	Navision 2015	Castor	Quantitative	.sav	0-10 GB

2.2 Do you reuse existing data?

- Yes, please specify

In this retrospective study, we use pseudonymized data from HiX and Navivision 2015.

2.3 Describe who will have access to which data during your study.

Type of data	Who has access
Direct identifying personal data	Research team with care relationship to patient, Datamanager
Key table linking study specific IDs to Patient IDs	PI (with care relationship to patient), Datamanager
Pseudonymized data	Research team with care relationship to patient, Datamanager

2.4 Describe how you will take care of good data quality.

Data from patients will be collected in an electronic Case Report Form (eCRF) in a certified Data Capture Tool: Castor. In the eCRF, skips and validation checks are built in.

#	Question	Yes	No	N/A
1.	Do you use a certified Data Capture Tool or Electronic Lab Notebook?	x		
2.	Have you built in skips and validation checks?	x		
3.	Do you perform repeated measurements?		x	
4.	Are your devices calibrated?			x
5.	Are your data (partially) checked by others (4 eyes principle)?		x	
6.	Are your data fully up to date?	x		
7.	Do you lock your raw data (frozen dataset)			
8.	Do you keep a logging (audit trail) of all changes?		x	
9.	Do you have a policy for handling missing data?	x		
10.	Do you have a policy for handling outliers?			x

2.5 Specify data management costs and how you plan to cover these costs.

#	Type of costs	Division ("overhead")	Funder	Other (specify)
1.	Data Capture Tool license fee	x		
2.	Storage	x		
3.	Archiving	x		
4.	Time of datamanager	x		

2.6 State how ownership of the data and intellectual property rights (IPR) to the data will be managed, and which agreements will be or are made.

UMC Utrecht is and remains the owner of all collected data for this study. Our data cannot be protected with IPR, but its value will be taken into account when making our data available to others, when setting up Research Collaborations and when drawing up Data Transfer Agreement(s).

3. Personal data (Data Protection Impact Assessment (DPIA) light)

Will you be using personal data (direct or indirect identifying) from the Electronic Patient Dossier (EPD), DNA, body material, images or any other form of personal data?

- Yes, go to next question

I will process personal data. I have consulted the division datamanager and I do not have to complete a full DPIA. I therefore fill out this DPIA light and proceed to 3.1.

3.1 Describe which personal data you are collecting and why you need them.

Which personal data?	Why?
Patient demographics (Age, gender)	To describe our study population
Medical History (cataract surgery, IOL placement)	To assess elegibility for the study
Contact Lens characteristics (type, wearing modality, replacement modality)	To assess our research question
Ophthalmology data (visual acuity, axial length, complications)	To answer the research question

3.2 What legal right do you have to process personal data?

- No objection, please explain

The division data manager will perform the no-objection check after all UMCU data is collected.

3.3 Describe how you manage your data to comply to the rights of study participants.

The data are pseudonymized and the linking table to personal data is saved. An authorized person manages the linking table, can re-identify study participants when necessary and deliver, correct or delete the data.
Right of Objection: no-objection check

3.4 Describe the tools and procedures that you use to ensure that only authorized persons have access to personal data.

1. We use the secured Research Folder Structure that ensures that only authorized personnel has access to personal data, including the key table that links personal data to the pseudoID.
2. We make use of a certified Electronic Data Capture (EDC) tool (Castor).

3.5 Describe how you ensure secure transport of personal data and what contracts are in place for doing that.

Data will be collected via Castor. We have a Research Agreement and/or Data Transfer Agreement with VUmc. The agreement is stored at location: .....

4. Data Storage and Backup

4.1 Describe where you will store your data and documentation during the research.

The digital files will be stored in the secured Research Folder Structure of the UMC Utrecht. We will need +/- 2 GB storage space, so the capacity of the network drive will be sufficient.

4.2 Describe your backup strategy or the automated backup strategy of your storage locations.

1. All (research) data is stored on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT).

2. During data collection, automatic backups will be made in the Electronic Data Capture Tool Castor. Upon completion of data collection, all data are exported and saved in the Research Folder Structure where they are automatically backed up by the UMC Utrecht backup system.

5. Metadata and Documentation

5.1 Describe the metadata that you will collect and which standards you use.

For the data collected in Castor, a datadictionairy will be automatically generated. We do not use metadata standards yet.

5.2 Describe your version control and file naming standards.

We will distinguish versions by indicating the version in the filename of the master copy by adding a code after each edit, for example V1.1 (first number for major versions, last for minor versions). The most recent copy at the master location is always used as the source, and before any editing, this file is saved with the new version code in the filename. The file with the highest code number is the most recent version. Every month, we will move minor versions to a folder OLD. The major versions will be listed in a version document (projxVersDoc.txt), stating the distinguishing elements per listed version.

6. Data Analysis

6 Describe how you will make the data analysis procedure insightful for peers.

I have written an analysis plan in which I state why I will use which data and which statistical analysis we plan to do in which software. The analysis plan is stored in the project folder, so it is findable for my peers.

7. Data Preservation and Archiving

7.1 Describe which data and documents are needed to reproduce your findings.

The data package will contain: the raw data, the study protocol describing the methods and materials, the script to process the data, the scripts leading to tables and figures in the publication, a codebook with explanations on the variable names, and a ‘read_me.txt’ file with an overview of files included and their content and use.

7.2 Describe for how long the data and documents needed for reproducibility will be available.

Data and documentation needed to reproduce findings from this non-WMO study will be stored for at least 15 years.

7.3 Describe which archive or repository (include the link!) you will use for long-term archiving of your data and whether the repository is certified.

After finishing the project, the data package will be stored at the UMC Utrecht Research Folder Structure and is under the responsibility of the Principal Investigator of the research group. When the UMC Utrecht repository is available, the data package will be published here.

7.4 Give the Persistent Identifier (PID) that you will use as a permanent link to your published dataset.

TBD

8. Data Sharing Statement

8.1 Describe what reuse of your research data you intend or foresee, and what audience will be interested in your data.

TBD

8.2 Are there any reasons to make part of the data NOT publicly available or to restrict access to the data once made publicly available?

TBD

8.3 Describe which metadata will be available with the data and what methods or software tools are needed to reuse the data.

TBD

8.4 Describe when and for how long the (meta)data will be available for reuse

TBD

8.5 Describe where you will make your data findable and available to others.

TBD