Plan Overview

A Data Management Plan created using DMPonline

Title: The clinical course of papillitis in pediatric uveitis and the use of optical coherence tomography for monitoring

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Template: UMC Utrecht DMP

Project abstract:

Rationale: Uveitis in childhood is a potentially blinding inflammatory eye disease. In part of these children the optic disc gets involved in the inflammatory process, sometimes without other posterior segment pathology, presenting as papillary edema and/or leakage called papillitis. Although the clinical appearance can be subtle and therefore difficult to diagnose, it can potentially lead to (permanent) visual field defects and visual impairment if not treated adequately. Adequate monitoring of papillitis in the course of uveitis is necessary for the best management of uveitis and has direct therapeutic implications. Currently in daily clinical practice, the papillitis is visualized with fluorescence angiography (FA): an invasive investigation, which puts stress on a child and its parents and cannot be repeated frequently. In children with anterior uveitis FA is practically never being performed, because of the lack of retinal involvement. However, up to almost 30% of these children show clinical signs of papillitis. The tools for reliable non-invasive clinical monitoring of papillitis in children with uveitis are lacking and the clinical course of papillitis in different forms of pediatric uveitis is not specifically clarified. Objective: to describe the clinical course of patients with papillitis in pediatric uveitis, and to evaluate the usability of retinal nerve fiber layer (RNFL) thickness measurement with optical coherence tomography (OCT) as a reliable, quick and non-invasive tool for monitoring papillitis in children with uveitis. Study design: Retrospective study. Study population: Children with pediatric uveitis (onset before 16 years of age), examined at the UMC Utrecht between 2010 and 2020 in whom FA is performed. Main study parameters/endpoints: The main study parameter is the RNFL thickness on OCT at diagnosis of uveitis and during follow-up in relation and correlation to FA score (overall and specifically of the optic disc hyper fluorescence at 5-10 minutes), according to USUWOG criteria and clinical activity of uveitis (anterior an vitreous cell grade). Nature and extent of the burden associated with participation, benefit and group relatedness: There are no risks for the patient due to the retrospective analysis of the data. No additional test will be performed.

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The clinical course of papillitis in pediatric uveitis and the use of optical coherence tomography for monitoring

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)*	
METC number *(only for human-related research)*	TBD
DEC number *(only for animal-related research)*	
Acronym/short study title	MPPU
Name Research Folder	xx-xxx_MPPU
Name Division	Surgery
Name Department	Ophthalmology
Partner Organization	
Start date study	TBD
Planned end date study	
Name of datamanager consulted*	Dax Steins
Check date by datamanager	13-01-2021

1.2 Select the specifics that are applicable for your research.

- Monocenter study
- Non-WMO
- Retrospective study

2. Data Collection

2.1 Give a short description of the research data.

For this study, we aim to evaluate the use of optical coherence tomography (OCT) as a potential tool for monitoring papillitis in patients with pediatric uveitis, specifically the measurement of retinal nerve fiber layer (RNFL) by OCT. Consequently, we shall retrospectively collect health care data from patients with papillitis and pediatric uveitis, who have undergone fluorescein angiography at the UMC Utrecht between 01-01-2010 and 01-06-2020.

According to our sample size calculation a minimum of 30 patients is needed to anwser our main research question.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	30	EPD (HIX)	Research Data Platform (RDP)	Quantitative	.xlsx	0-10 GB
Human	>30	FORUM viewer	Excel	Quantitative	.xlsx	0-10 GB

Pseudonymized health care data from 30 patients will be collected via our Research Data Platform (RDP) by the dHS data manager in an Excel file. Subsequently, additional data that cannot be collected through our RDP will be manually collected from our electronic patient records (HiX) by a member of the research team.

Data from OCT scans and fluorescein angiography will be manually extracted form FORUM viewer by members of our research team. All data will be combined into one Excel file.

One patient can have multiple OCT and/or FA scans, therefore the amount of OCT and/or FA scans will be more than 30. The mimimum follow-up time is 6 months.

2.2 Do you reuse existing data?

- Yes, please specify

In this retrospecive study, we use pseudonymized data made available for research by Research Data Platform (RDP). If this data is incomplete, additional data will be extracted manually from HIX.
We reuse data from patients who gave broad consent for the "Registry Kinderuveitis" (METC 18-682) and "BEAT-U" (METC 19-178).

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

1. My division datamanager receives a datamart from the Research Data Platform (RDP) that contains direct identifying personal data (e.g. date of birth) and pseudonymized data. The datamanager is authorized to link different datasets of the selected patient group and thus has access to personal data such as patientID. The key table linking study specific IDs to patient IDs is available to the datamanager and members of the research team with a care relationship to the patient. Other members of the research team receive a pseudonymized dataset and have no access to direct personal data or the key table.

Type of data	**Who has access**
Direct identifying personal data	Research team, dHS Datamanager
Key table linking study specific IDs to Patient IDs	PI, Research team, dHS Datamanager
Pseudonymized data	Research team, dHS Datamanager

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

1. We do not use a certified Data Capture Tool. Research data from patients will be collected in an Excel spreadsheet. Data from HiX and FORUM viewer will combined in the same Excel spreadheet. Data quality will be checked by members of the research team. After data collection, the dataset will be frozen before analysis.

#	**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)	X		
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.	Time of datamanager	X		
2.	Storage	X		
3.	Archiving	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

2. I will process personal data. I have consulted the division data manager 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?
PatientID	To collect data from the EPF
Democraphics (Age, Gender, type of uveitis)	To describe our study population
Medical history (Diagnosis of an underlying systemic disease)	To describe our study population
Type of Medication (topical corticosteroids, systemic corticosteroids, immunomodulatory therapy, biological agents, etc.)	To describe our study population

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

- Other, please explain

Broad consent, "Registry Kinderuveitis" (METC 18-682).

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

Right	Answers
Right of Access	Research data are coded, but can be linked back to personal data, so we can generate a personal record at the moment the person requires that. This needs to be done by an authorized person.
Right of Rectification	The authorized person will give the code for which data have to be rectified.
Right of Objection	We use informed consents.
Right to be Forgotten	In the informed consent we state that the study participant can stop taking part in the research. Removal of collected data from the research database cannot be granted because this would result in a research bias.

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

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.

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

We will not transport any personal data outside the UMCU network drives.

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.

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

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

5. Metadata and Documentation

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

The standard terminology used in Ophthalmology will be used (such as SUN criteria).

- Overall research project: information about how, when and by whom what data was collected (e.g. description, format, date, creator, etc.).
- Data dictionary: lists basic definitions of a database, including labels and values in the dataset.
- The metadata and data documentation will be documented in the Excel speadsheet.

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.

Statistical analysis of the data will be performed with SPSS. The scrips (syntax) will contain comments, such that every step in the analysis is documented and pears can read why I made certain decisions during the analysis phase.

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 (with syntaxes), 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.

The research data will be archived on the research network disc of the division for 15 years after the study has ended.

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.

The data that are used in publication XXX are published with the publication and are to be found under the PID XXX.
** I will update 'XXX' in this answer when available.*

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?

- No, all data generated in this project will be made publicly available without any restrictions

TBD. Most likely with an embargo period.

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

All data and documents in the data package mentioned in 7.1 will be shared under restrictions.

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

- (Meta)data will be available upon completion of the project

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

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.