Plan Overview

A Data Management Plan created using DMPonline

Title: Efficacy of customized corneal cross-linking versus standard corneal cross-linking in patients with progressive keratoconus

Creator: Marc Muijzer

Principal Investigator: R.P.L. Wisse

Data Manager: Dax Steins

Project Administrator: R.P.L. Wisse

Affiliation: UMC Utrecht

Template: UMC Utrecht DMP

ID: 77732

Start date: 01-09-2021

End date: 31-12-2022

Last modified: 06-07-2021

Efficacy of customized corneal cross-linking versus standard corneal cross-linking in patients with progressive keratoconus

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)*	NA
Acronym/short study title	c-cross
Name Research Folder	xx-xxx_c-cross
Name Division	heelkundige specialismen
Name Department	oogheelkunde
Partner Organization	MUMC+
Start date study	1-9-2021
Planned end date study	1-9-2023
Name of datamanager consulted*	Dax Steins
Check date by datamanager	6-7-2021

1.2 Select the specifics that are applicable for your research.

- Clinical study
- Multicenter study
- Prospective study
- WMO
- Use of Questionnaires
- Interventional study

Centra's: Maastricht UMC, UMC Utrecht, UMC Groningen

2. Data Collection

2.1 Give a short description of the research data.

Research aim:
Research population: Keratoconus patient schedulded for crosslinking treatment
Data flow: timeframe en methods...

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
human	51	EPD (Hix)	castor	quantitative/text		0-10 gb
human	51	eCRF	castor	quantitative	.csv	0-10 gb
human	51	epro	castor	qualitative/quantitative		0-10 gb

2.2 Do you reuse existing data?

- No, please specify

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, Datamanager
Key table linking study specific IDs to Patient IDs	research team, Datamanager
Pseudonymized data	Research team, Datamanager, monitor

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

#	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.	Design of eCRF		x	
2.	Storage	x		
3.	Archiving	x		
4.				
5.				

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.

1. UMC Utrecht is and remains the owner of all collected data for this study. The data is collected in a relatively large patient group and is very valuable for further, broader studies in Europe. It may for example be used to find study subjects for future treatment studies. 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). -> check wie eigenaar is.

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 checked the full DPIA checklist 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?**
Name and email address of participants	To be able to invite participants for taking part in the research and to send them questionnaires
Gender, age	To describe our study population
Ophthalmologic clinical examination results (including clinical outcomes and medical imaging results, but not the images itself)	To collect study data (nader te specificeren)

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

- Study-specific informed consent

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

Right of Objection: We use informed consent.
WMO-compliant research with informed consent. All research data is coded, with the key for decoding managed by the PI.

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). To send surveys, email address will be used in the EDC, but this is encrypted for the users in such a way that users can send emails to subjects without seeing the actual email address. No personal data other than email address will be used in the EDC.

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

1. We have a Research Agreement and/or Data Transfer Agreement with Maastricht UMC . The agreement is stored at location: secured research folder structure, xx-xxx_c-cross submap B

4. Data Storage and Backup

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

1. The digital files will be stored in the secured Research Folder Structure of the UMC Utrecht. We will need +/- 50 GB storage space, so the capacity of the network drive will be sufficient. Paper dossiers will be stored safely in a locked cabinet in a locked room in the UMC Utrecht. A project specific procedure is in place for access to the paper dossiers. Documentation of this procedure is stored in the Research Folder Structure.

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.

1. For the data collected in Castor, I prepared a codebook of my research database. We do not use metadata standards yet.

5.2 Describe your version control and file naming standards.

1. 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.

nvt

7. Data Preservation and Archiving

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

1. The data package will contain: the raw data, the study protocol describing the methods and materials, 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.

In view of the regulation for Clinical Trials, I need to store all data for at least 15 years with the goal to be able to go back to patient level.

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.

1. We will use the repository DANS (to be determined by the MUMC which specific repository) that is certified with the

CoreTrustSeal.

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

1. I will be using a DOI-code and will update this plan as soon as I have the code.

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.

to be determined

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?

- Yes (please specify)

to be determined

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

to be determined

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

- Other (please specify)

to be determined

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

to be determined