The visual outcome of children after epilepsy surgery

A Data Management Plan created using DMPonline

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Funder: UMC Utrecht

Template: UMC Utrecht DMP

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1. General features

DMP template version	29 (don't change)
ABR number *(only for human-related research)*	N/A
METC number *(only for human-related research)*	Not yet reviewed
DEC number *(only for animal-related research)*	N/A
Acronym/short study title	VOESIC
Name Research Folder	Visual Outcome Epilepsy Surgery
Name Division	Heelkundige specialismen
Name Department	Oogheelkunde
Partner Organization	N/A
Start date study	To be determined
Planned end date study	13-11-2020
Name of datamanager consulted*	D. Steins
Check date by datamanager	

- Non-WMO
- Retrospective study
- Monocenter study

2. Data Collection

A pseudonymized/anonymized dataset will be generated by our division Datamanager using a dedicated datamart (Research Data Platform) from the department of Ophtalmology. This dataset will be exported in an Excel spreadheet and stored according to the UMCU policy.
Additional information that cannot be generated by our dHS datamanger will be manually extracted by the PI with a care relationship to the patient.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	mimimum of 28	SAS datamart	Excel	Quantitative data/database	.xlsx	1GB

- Yes, please specify

Anonymized patientdata from the department of Ophthalmology will be reused in this study.

Type of data	Who has access
Direct identifying personal data	Principal Investigator (with care relationship to included patients)
Anonymized database	Researchteam, Datamanager
Key linking table	PI (with care relationship), Division Datamanager
Pseudonymized data	PI and Research team with care relationship to the included patients

#	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		

#	Type of costs	Division ("overhead")	Funder	Other (specify)
1.	Time of datamanager	x		
2.	Storage	x		
3.	Archiving	x		
4.				
5.				

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).

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

- Yes, go to next question

Which personal data?	Why?
Baseline characteristics (such as gender, age at surgery, age at diagnosis, epilepsy etiology, location etiology, comorbidities, epilepsy frequency, surgery type, surgery side, surgery date, post-operative complications, anti-epileptic drugs, seizure freedom after 3, 6 months and 1, 2 years follow-up)	To describe the study population
Visual outcomes (visual acuity: methods, outcomes; visual field: methods, outcomes; orthoptic assessment: fixation, pursuit eye movements, visual attention, CVI-like behavior after follow-up of respectively 3, 6 months, 1 and 2 years)	To support hypothesis

- No objection, please explain

The PI has a care relationship to the patients and will perform the no-objection check prior to the data collection and after the data collection has finished.

The data are pseudonymized/anonymized by the dHS datamanager and the key-linking table to re-identify patients is saved in a secure research folder with seperate privileges determined by your relationship to the patient.

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.
Furthermore, dataset will be password protected.

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

4. Data Storage and Backup

The digital files will be stored in the secured Research Folder Structure of the UMC Utrecht (L:\pathname...) We will need +/- 50 GB storage space, so the capacity of the network drive will be sufficient.

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

5. Metadata and Documentation

The datadictionary and overall research project will be available in the Research Folder for all involved researchers.

We will distinguish versions by using the date, for example ddmmyyyy_documentname_v1.0_initials

6. Data Analysis

Research data will be collected in an Excel spreadsheet and imported for statistiscal analysis in SPSS Statistics 24. The statistical analysis procedure can be found in detail in our research proposal.
The analysis plan is stored in the project folder, so it is findable for my peers at UMC Utrecht. Peers will be able to repeat the analysis based on my overview.

7. Data Preservation and Archiving

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.

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

To be determined later in this study. The UMCU is in negotiation with a possible public respository DataverseNL.

I will be using a DOI-code and will update this plan as soon as I have the code. A PID will also be published if there is a scientific publication or published conference paper.

8. Data Sharing Statement

To be determined later in this study.

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

To be determined.

- Other (please specify)

To be determined.

To be determined.