DMP title

Project Name Effects of oxytocin treatment in boys with autism with and without intellectual disability: A verification trial with long-term follow-up - DMP title

Principal Investigator / Researcher Kaat Alaerts

Description The principal objective of this study is to evaluate the efficacy of multiple-dose oxytocin treatment on core autism symptoms using standardized assessments in children with ASD and comorbid ID (intellectual disability). The study will also encompass exploratory assessments of social reciprocity and stress physiology during semi-structured socio-interactive sessions administered throughout the trial, allowing objective quantifications in more â€˜naturalistic settingsâ€™ for capturing treatment responses. Considering recent notions of the importance of context in which oxytocin treatment is administered, the oxytocin treatment will be combined with targeted semi-structured socio-interactive training sessions. The standardized pairing of the oxytocin nasal spray administrations with social training, will allow further elucidating whether clinical efficacy can possibly be augmented from administering oxytocin in a supportive socio-interactive context. In addition to gaining insights into the clinical efficacy of oxytocin treatment, another major sub-aim of the current trial will be to obtain a qualitative evaluation of the expectations and perceptions of oxytocin treatment by conducting semi-structured interviews with the participating children and parents. Thus far, only little is known about the expectations and perceptions of oxytocin treatment in people with ASD. The nature of the neuropeptide and how it is presented on the internet (i.e., as â€˜love hormoneâ€™ or â€˜cuddling hormoneâ€™) lead to various expectations of its effects. Information and discussions about oxytocin are currently found on ASD advocacy websites. As the expectations and perceptions of a biological intervention may have a huge influence on how the person and his/her environment evaluate the effects of intervention, it is recommended that deeper insights are gained into these issues.

Institution KU Leuven

1. General Information

Name applicant

Kaat Alaerts
Jean Steyaert
Bart Boets

FWO Project Number & Title

T002620N - Oxytocin treatment in boys with autism
(part by C24M/21/045 - Oxytocin treatment in boys with autism - qualitative analysis)

Affiliation

- KU Leuven

2. Data description

Will you generate/collect new data and/or make use of existing data?

- Generate new data

Describe in detail the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a table (see example) or as a data flow and per WP or objective of the project. If you reuse existing data, specify the source of these data. Distinguish data types (the kind of content) from data formats (the technical format).

The project entails a randomized, double-blind, placebo-controlled clinical trial in which a total of 120 boys with ASD and comorbid ID will be randomly allocated to receive a **four-week treatment** with oxytocin (n=60) or placebo (PL) (n=60) nasal spray. The nasal spray administrations will be combined with a socio-interactive training session, administered three times weekly, 12 sessions in total.

Type of Data	Origin	Format	Volume
Questionnaires about core autism symptoms and other socio-communicative constructs -The Social Responsiveness Scale-Children (SRS) -The Social Communication Questionnaire (SCQ) -The Repetitive Behavior Scale-Revised (RBS-R) -Child Behavior Checklist (CBCL)	mPath, REDCap	.csv	+/- 5MB
Stress physiology recordings	skin conductance, respiration, electrocardiography (ECG) and headband electroencephalography + webcam videos	.mat, .mp4	stress recordings: Appr. 50 MB webcam videos: to be determined
Eye tracking	Core eye-tracking glasses (Pupil Labs GmbH, Germany)	.mp4 and software specific data format	to be determined
Hormonal assessments (oxytocin, cortisol levels)	Saliva samples with Salivette cotton swaps	small, individual tubes	/
Qualitative interviews	audio recordings	.mp3 (transcribed to word/pdf format)	to be determined
Gut Microbiome (optional)	a fecal (stool) sample		/
Mouth Microbiome	mouth swab (FLOQSwab)		/
Social reciprocity ratings	mPath or paper versions	(transcribed to) .csv	+/- 5MB

3. Legal and ethical issues

Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to your file in KU Leuven's Register of Data Processing for Research and Public Service Purposes (PRET application). Be aware that registering the fact that you process personal data is a legal obligation.

- Yes

Yes, a PRET application will be submitted in the future.

Short description of the kind of personal data that will be used:

All personal data will be collected via electronic surveys like REDCap and mPath.

Ordinary personal data: name of the children and their parents, parents' contact details: only acquired for communicating with the participants throughout the course of the study, will not be used for long-term storage.

Sensitive personal data: age, gender, ASD symptom severity, standardized questionnaires, IQ measurement, Stress physiology recordings, Eye tracking data, hormonal assessments, microbiome assessments and facial expressivity.

All research-relevant personal data will be de-identified and stored in coded form on the protected L-drive (during study, transferred to K-drive after study completion) of KU Leuven or on the independent and secured database and data management system (REDCap). This database is password-protected and only accesible by the researchers of this study.

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, add the reference to the formal approval by the relevant ethical review committee(s)

- Yes

A PRET application will be submitted in the future.

Does your work possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?

- No

Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions are in place?

- No

4. Documentation and metadata

What documentation will be provided to enable reuse of the data collected/generated in this project?

- For questionnaires: Metadata (e.g. timestamp, electronic instructions) are automatically captured in REDCap or mPath.
- Standard operating procedures will be written to describe how to collect and analyse data from the measurements of stress physiology and social reciprocity .
- Using RedCap, a Data Dictionary Codebook will be generated containing variable-level information for all captured information: Variable / Field name, Field Label (including question text) and Field Attributes (including Field Type, Validation, Choices, Calculations etc.)

Will a metadata standard be used? If so, describe in detail which standard will be used. If no, state in detail which metadata will be created to make the data easy/easier to find and reuse.

- No

REDCap offers the possibility to download a XML file of the metadata, which consists of the following information: User Roles, Data Access Groups, Data Quality Rules, Surveys and survey settings, order of survey queue.

REDCAp also keeps a log of when the questionnaires/surveys are filled in, when someone makes adjustments to the instruments or data. Also, metadata (e.g. timestamp, electronic instructions) are automatically captured during survey completion in REDCAp

The skin conductance device, electrocardiography (ECG) and headband electroencephalography devices generate metadata like the instrument settings and the timing of the measurements.

5. Data storage and backup during the FWO project

Where will the data be stored?

Paper data like the ICF forms will be kept in a locked cabinet in the office of the PI at KU Leuven.

Other pseudonymized data will be kept electronically in RedCap, mPath or in a secured folder on the KU Leuven L-drive. The data will only be accesible by the researchers of this project.

In a separate folder on the L-drive of the KU Leuven servers, a password protected document will be kept containing the patient identification log; this will be the only link between the real identity of the participants and their allocated subject ID code (pseudonymization code).

How is backup of the data provided?

The data will be stored on RedCap and a central KU Leuven server (L:drive) with automatic daily back-up procedures.

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely. If no or insufficient storage or backup capacities are available then explain how this will be taken care of.

- Yes

RedCap is hosted on central ICTS webservices and provides unlimited capacity.

The minimum for large volume storage provided by the KU Leuven ICTS-hosted L:drive is 5 TB. It is expected this volume is sufficient for the current project. A disaster recovery (mirror) copy of the data is included in this fee.

What are the expected costs for data storage and back up during the project? How will these costs be covered?

The price to set-up a RedCap projects is € 80 per year. Data storage on L:drive storage will result in a cost of € 569,2 per year (for max. 5 TB of data). Costs for data storage will be covered by **personal funds** of the involved PI (Kaat Alaerts) and support funds from the Rehabilitation sciences department.

Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

- All included storage facilities (RedCap, L:drive) are incorporated within secured KU / UZ Leuven environments, are password-protected (including smartphone-based multi-factor identification) and are only accessible by registered collaborating researchers.
- All data files will be collected, processed and stored in a de-identified format by means of subject ID codes (i.e. pseudonymization). These datafiles will not contain information that would allow participant identification.
- Personal data collected on paper (e.g. informed consent forms) are stored in a locked cabinet onsite (during data collection: accessible only to study personnel; after data collection: accessible solely by PI of the study).

6. Data preservation after the FWO project

Which data will be retained for the expected 5 year period after the end of the project? In case only a selection of the data can/will be preserved, clearly state the reasons for this (legal or contractual restrictions, physical preservation issues, ...).

All generated research data will be archived for minimal **25 years after study completion** conform the FWO and KU Leuven RDM policy, as well as good clinical practice guidelines for archiving clinical trial data.

Where will the data be archived (= stored for the longer term)?

The generated research data, the accompanying metadata and all documentation necessary to

reuse the data will be transferred to the K:drive designed for long-term data archiving (managed by KU Leuven ICTS with automatic back-up procedures).

What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?

Pricing for data storage on the K:drive includes € 11,38 per 100 GB (with 50% of the cost covered by Group Biomedical Sciences). In view of the expected size of the database (including raw and preprocessed data), estimated cost of long-term data storage will be € 56,9 per year for **500 GB**.

7. Data sharing and reuse

Are there any factors restricting or preventing the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

- No

Which data will be made available after the end of the project?

We plan to make (parts of) the de-identified, and pseudonymized raw data collected during the study available through the Open Science Framework (https://osf.io/) online repository or the recently launched KU Leuven Research data Repository.

All clinical trial results will also be posted on the EUDRACT clinical trial study entry within 6 months after study completion (last visit of the last participant).

Where/how will the data be made available for reuse?

- In an Open Access repository
- Upon request by mail

When will the data be made available?

- Immediately after the end of the project
- Upon publication of the research results

We plan to make (parts of) the de-identified, and pseudonymized raw data collected during the study available through the Open Science Framework (https://osf.io/) online repository or the recently launched KU Leuven Research data Repository.

All clinical trial results will also be posted on the EUDRACT clinical trial study entry within 6 months after study completion (last visit of the last participant).

Who will be able to access the data and under what conditions?

Sharing of de-identified, pseudonymized data upon request by email will be considered depending on the planned reuse. Only uses for research purposes will be allowed and commercial reuse will be excluded.

What are the expected costs for data sharing? How will the costs be covered?

Sharing on OSF and RDR are not anticipated to yield any additional costs.

8. Responsibilities

Who will be responsible for data documentation & metadata?

The involved researchers, CRA Grindl Wilmots and PI Kaat Alaerts.

Who will be responsible for data storage & back up during the project?

Back-up and immediate storage: all research personnel

Long-term storage: PI Kaat Alaerts

Who will be responsible for ensuring data preservation and reuse ?

PI Kaat Alaerts

Who bears the end responsibility for updating & implementing this DMP?

The PI (Kaat Alaerts) bears the end responsibility of updating & implementing this DMP.