Experimental fMRI study on the comparison of the brain function effects of a single dose of guanfacine and lisdexamfetamine relative to placebo in children and adolescents with ADHD

NCT03333668

26/04/2018

IRAS ID: 231293

Participant Identification Number for this study:

Title of Project: **Experimental fMRI study on the comparison of the brain function effects of a single dose of Guanfacine and Lisdexamfetamine relative to placebo in children and adolescents with ADHD.**

Name of Researcher: Olivia Kowalczyk/Prof Katya Rubia/Prof Mitul Mehta

CONSENT FORM (Parent)
(Version 2 26/04/2018)

Please initial box

1	I confirm that I have read and understand the information sheet dated version 5 27/03/2019 for the above study and have had the opportunity to ask questions.	☐
2	I understand that my child's participation is voluntary and that he/she is free to withdraw at any time without giving any reason, without his/her medical care or legal rights being affected.	☐
3	I understand that relevant sections of my child's medical notes and data collected about him/her may be looked at by individuals from the research group, from regulatory authorities or from the NHS Trust, where it is relevant for my child taking part in this research. I give permission for these individuals to have access to my child's records.	☐
4	I agree for my child to take part in the scanning study.	☐
5	I agree that my child's GP will be contacted regarding participation in this study.	☐
6	I agree that my child's GP and the study team will be contacted if anything abnormal is detected in this brain scan.	☐

7	I agree that my child's brain imaging, cognitive and clinical data may be used in an anonymised form in future research.	☐
8	I agree that my child's data can be transferred to other researchers for purposes connected with my participation in this study but that this will be anonymised. This data will be published in scientific journals and presented at conferences or meetings.	☐
9	I agree to take part in the study myself and fill in some questionnaires about my child's behaviour.	☐
10	I consent for the interview with my child and myself to be audio-recorded for the purposes of research and with the safeguards of secure storage and access by the research team only.	☐

Optional

11	I agree that my child may be contacted for future research studies.	☐

Name of Parent/Caregiver	Date	Signature

Name of Person taking consent (if different from researcher)	Date	Signature

I confirm that I have explained the study to the participants in all relevant details and have answered any questions honestly and fully ☐

Researcher	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

IRAS ID: 231293

Participant Identification Number for this trial:

Title of Project: **Experimental fMRI study on the comparison of the brain function effects of a single dose of Guanfacine and Lisdexamfetamine relative to placebo in children and adolescents with ADHD.**

Name of Researcher: Olivia Kowalczyk/Prof Katya Rubia/Prof Mitul Mehta

ASSENT FORM (under 16)

To be completed once parent/guardian has consented (Version 2 26/04/2018)

Please initial box

1	I confirm that I have read and understand the information sheet dated version 5 27/03/2019 for the above study and have had the opportunity to ask questions.	☐
2	I understand that my participation is voluntary and I can stop and leave the study whenever I want to without giving a reason and that this does not affect my medical care.	☐
3	I understand that some researchers or doctors may look at my medical notes if they need to find out more information that is relevant to the research. I agree to this.	☐
4	I agree to take part in the scanning study.	☐
5	I agree that my GP (doctor) will be contacted regarding participation in this study.	☐
6	I agree that my GP and the study team will be contacted if anything unusual is being detected in the brain scan.	☐

7	I agree that my brain imaging, cognitive, and clinical data may be used in an anonymised form in future research.	☐
8	I agree that my data can be given or shown to other researchers but that this will be anonymised. This data will be published in scientific journals and presented at conferences or meetings.	☐
9	I consent for the interview to be audio-recorded for the purposes of research and with the safeguards of secure storage and access by the research team only.	☐

Optional

9	I agree to be contacted for future research studies.	☐

Name of Adolescent	Date	Signature

Name of Person taking consent (if different from researcher)	Date	Signature

I confirm that I have explained the study to the participants in all relevant details and have answered any questions honestly and fully. ☐

Researcher	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

IRAS ID: 231293

Participant Identification Number for this study:

Title of Project: **Experimental fMRI study on the comparison of the brain function effects of a single dose of Guanfacine and Lisdexamfetamine relative to placebo in children and adolescents with ADHD.**

Name of Researcher: Olivia Kowalczyk/Prof Katya Rubia/Prof Mitul Mehta

CONSENT FORM (over 16)
(Version 2 26/04/2018)

Please initial box

1	I confirm that I have read and understand the information sheet dated version 5 27/03/2019 for the above study and have had the opportunity to ask questions.	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	☐
3	I understand that relevant sections of my medical notes and data collected about me may be looked at by individuals from the research group or from the NHS Trust, where it is relevant for my taking part in this research. I give permission for these individuals to have access to my records.	☐
4	I agree to take part in the scanning study.	☐
5	I agree that my GP will be contacted regarding participation in this study.	☐
6	I agree that my GP and the study team will be contacted if anything unusual is being detected in the brain scan.	☐

7	I agree that my brain imaging, cognitive, and clinical data may be used in an anonymised form in future research.	☐
8	I agree that my data can be transferred to other researchers for purposes connected with my participation in this study but that this will be anonymised. This data will be published in scientific journals and presented at conferences or meetings.	☐
9	I consent for the interview to be audio-recorded for the purposes of research and with the safeguards of secure storage and access by the research team only.	☐

Optional

10	I agree to be contacted for future research studies.	☐

Name of Adolescent	Date	Signature

Name of Person taking consent (if different from researcher)	Date	Signature

I confirm that I have explained the study to the participants in all relevant details and have answered any questions honestly and fully ☐

Researcher	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes