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Investigation of WCFS1 on the gut microbiota of autistic spectrum disorder (ASD) children

Submission date	Recruitment status	[X] Prospectively registered
16/11/2011	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/12/2011	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/04/2019	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and aims?
Autism spectrum disorders (ASD) are a group of disorders which predominantly manifest behaviourally. However ASD children also commonly suffer gut symptoms, such as diarrhoea, constipation ad abdominal pain. The bacteria that live within the gut may play a role in the gut symptoms. Children with ASD have higher levels of certain gut bacteria (such as Clostridium) and have different types of bacteria, compared to non-ASD children. Probiotics (functional foods) are good or beneficial bacteria used to modify the composition and activity of the gut bacteria and can reduce certain gut symptoms. The main aim of the research is to examine whether feeding a probiotic called Lactobacillus plantarum WCFS1 can change the gut bacteria in ASD children (to be more like that on non-ASD children) and/or reduce gut symptoms.

Who can participate?
Children/adolescents with a clinical diagnosis of ASD, aged between 4-16, who have gut problems (minimum of 3 episodes in the last 6 months) and live within 75 miles of Reading study

What does the study involve?
The study will take place over 7-weeks, week 1 (baseline) will enable control data to be collected, and the following 6-weeks will be the feeding period. All parts of this study will take place in the participants home, with visits made by the investigators at times convenient for you and your child.
Your child will be randomly assigned to one of two groups (A or B) and will receive either the probiotic or placebo. Participants will consume a single portion of the treatment (probiotic or placebo) once a day. The study will be double blinded which means that neither the participants (you and your child) nor the investigators will know which treatment each child receives.
Microbiology: During the study period your child will provide 4 faecal samples, 2 at baseline and 2 in after feeding (week 6). The faecal samples will be analysed using a number of techniques to examine the gut bacteria and different biomarkers of gut function.
Gut symptoms: During the 7-weeks a daily diary will be filled in to assess bowel movement(s) /gut symptoms using a severity scale (requiring a tick answers). In addition, any medication your child is taking or has during the study will also have to be recorded, including the type, dosage, start and end date of the medication.
Behavioural assessment: A single diagnostic assessment of the childs ASD will be done using the

Autism Diagnosis Observation Schedule (ADOS). The ADOS is often used in research as a standardised measure of a childs ASD. A trained researcher from the Department of Psychology (University of Reading) will carry out this assessment. Further to this, you as the parent/guardian will be asked to complete the Social Communication Questionnaire (SCQ), to provide the developmental history of your child.
Your child will be asked to do a computerised test (Connors Continuous Performance Test; CPT) twice during the study (once each in weeks 0 and 6). This test measures selective and sustained attention. Whilst the child carries out the CPT, an infrared camera (Qbtest) will track your childs head movement which will provide feedback measures for hyperactivity, inattention and impulsivity.
Two parent/guardian questionnaires (Developmental Behaviour Checklist; DBC-P) about your childs behaviour will need to be completed (one in week 0 and the other in week 6). In addition, we would like your childs main teacher/teaching assistant to fill in the equivalent DBC-T in week 0 and week 6.

What are the possible benefits and risks of participating?
Possible benefits include overall improvements in your childs gut health. Lactobacillus plantarum WCFS1 is safe for human consumption and thus does not pose any risk during this study. Changes in diet can sometimes lead to gut symptoms in certain individuals. However, there is no known report of adverse effects following Lactobacillus plantarum WCSF1 feeding. In addition, each participant completing the study will be able to trial the probiotic by receiving 6-weeks supply (open-label follow on).

Where is the study run from?
The study will be run and funded by the University of Reading.

When is study starting and how long is it expected to run for?
The study will be open to participants from approximately January 2012 to June 2012.

Who is the main contact?
Holly Ambrose (trial co-ordinator)
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Contact information

Type(s)
Scientific

Contact name
Dr Anne McCartney

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
n/a

Study information

Scientific Title
Investigation of the effects of Lactobacillus plantarum WCFS1 supplementation on the gut microbiota and gut symptoms of children with autistic spectrum disorder (ASD)

Study objectives
Supplementation of the probiotic, Lactobacillus plantarum WCFS1 can modulate the gut microbiota associated with ASD, alleviate the gastrointestinal symptoms commonly suffered by ASD children, and affect the childs behaviour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NRES Committee South Central - Southampton, 19/08/2011 ref: 11/SC/0261
2. University of Reading Research Ethics Committee, 15/11/2011 ref: 11/56

Study design
Single-centre randomised double-blind placebo controlled parallel study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Autistic spectrum disorder

Interventions
A randomised placebo-controlled, double blind parallel feeding study testing a probiotic (Lactobacillus plantarum WCFS1) and a placebo. A single dose (4.5x1010 CFU/g) will be consumed daily for period of 6 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. To use multiple molecular techniques to investigate whether probiotic (Lactobacillus plantarum WCFS1) supplementation can modulate the gut microbiota associated with ASD
2. Particular interest will focus on quantification, and changes in the diversity and dynamics of lactic acid bacteria and clostridia

Secondary outcome measures
1. Can probiotic (Lactobacillus plantarum WCFS1) supplementation alleviate the gastrointestinal symptoms commonly suffered by ASD children?
2. Does probiotic (Lactobacillus plantarum WCFS1) supplementation affect the behaviour of ASD child?
Investigation of non-invasive inflammatory markers and faecal Clostridium toxicity genes and the effects of probiotic supplementation on these.

Overall study start date
01/01/2012

Completion date
31/01/2012

Eligibility

Key inclusion criteria
1. Children / adolescents with clinical diagnosis of ASD
2. Children with gut problems (minimum of 3 episodes in the last 6 months)
3. Aged between 4-16 years
4. Consent given by parent/guardian

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit

16 Years

Sex
Both

Target number of participants
Seventy children aged 4-16 with a diagnosis of ASD, who have gut symptoms.

Key exclusion criteria
1. Prebiotic / probiotic administration within the last 6 weeks
2. Involvement in another study involving drug/medication affecting gastrointestinal (GI) motility during the month prior to and throughout the study
3. Living more than 75 miles from Reading, UK

Date of first enrolment
01/01/2012

Date of final enrolment
31/01/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Food and Nutritional Sciences
Reading, Berkshire
United Kingdom
RG6 6AH

Sponsor information

Organisation
University of Reading (UK)

Sponsor details
c/o Dr Mike Proven
Whiteknights
Reading
England
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RG6 6AH

Sponsor type
University/education

Website
http://www.reading.ac.uk/

ROR
https://ror.org/05v62cm79

Funder(s)

Funder type
University/education

Funder Name
University of Reading (UK)

Alternative Name(s)
UoR

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration