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Urinary Steroid Metabolites in Autism

Submission date
20/06/2010

Recruitment status
No longer recruiting

Registration date
16/07/2010

Overall study status
Completed

Last Edited
08/03/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01197131

Protocol serial number
1.0

Study information

Scientific Title
Urinary Steroid Metabolites in Autism: An observational trial of 4 parallel groups

Acronym

USMiA

Study objectives
Widespread alteration of gene activation is contributed to alteration in hormone formation with elevated androgens in autism spectrum disorder

Ethics approval required
Old ethics approval format

Ethics approval(s)
The government ethics committee approved on the 12th of August 2010 (ref: FA8B-50.2-98 /2010-4)

Primary study design
Observational

Study design
Single centre observational 4 arm parallel group cohort trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Autism spectrum disorder, urinary steroid hormone metabolites

Interventions
Clinical investigation by an experienced paediatrician and /or diagnosis of autism spectrum disorder with ADI-R/ADOS schedule. Participants collect urine overnight. The time span and quantity of urine, participants weight, length and age are ascertained. Analysis of most known urinary steroid metabolites with Gas Chromatography Mass Spectrometry (GCMS).
Participants are divided into 4 parallel groups
1. Autistic boys
2. Autistic girl
3. Healthy control boys
4. Healthy control girls
Statistical analysis is carried out by linear regression.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Measurement of about 50 hormones and steroid metabolites
2. Enzymatic hormone formation and metabolism activity in autistic disorders and in healthy state

Key secondary outcome(s)
Relative hormone and steroid metabolite alteration due to age and gender

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Age between 5 and 15 years
2. Autism spectrum disorder ascertained by clinical investigation by an experienced paediatrician or Autism Diagnostic Interview - Revised (ADI-R) / Autism Diagnostic Observation Schedule (ADOS)
3. Healthy controls comparable in gender, age, weight and length to autistic participants

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 Years

Upper age limit
15 Years

Sex
All

Key exclusion criteria
1. Epilepsy
2. Other severe illness
3. Pregnancy
4. Psychotropic medication

Date of first enrolment
10/08/2010

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
Austria

Study participating centre

Moosweg 8A
Bärnbach
Austria
8572

Sponsor information

Organisation
Intersci Research Association (Austria)

Funder(s)

Funder type
Charity

Funder Name
Intersci Research Association (Austria)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration