

Urinary Steroid Metabolites in Autism

Submission date 20/06/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 16/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/03/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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