# Urinary Steroid Metabolites in Autism

Submission date 20/06/2010	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 16/07/2010	<b>Overall study status</b> Completed	<ul><li>Statistical analysis plan</li><li>Results</li></ul>
Last Edited 08/03/2019	<b>Condition category</b> Mental and Behavioural Disorders	<ul> <li>Individual participant data</li> <li>Record updated in last year</li> </ul>

### Plain English summary of protocol

Not provided at time of registration

## **Contact information**

#### **Type(s)** Scientific

**Contact name** Dr Johann Kurz

### **Contact details**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT01197131

Secondary identifying numbers 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 )

**Study design** Single centre observational 4 arm parallel group cohort trial

**Primary study design** Observational

**Secondary study design** Cohort study

**Study setting(s)** Hospital

**Study type(s)** Diagnostic

#### Participant information sheet

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

#### 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 measure

1. Measurement of about 50 hormones and steroid metabolites 2. Enzymatic bormone formation and metabolism activity in autistic disorder

2. Enzymatic hormone formation and metabolism activity in autistic disorders and in healthy state

#### Secondary outcome measures

Relative hormone and steroid metabolite alteration due to age and gender

### Overall study start date

10/08/2010

### 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

#### **Age group** Child

**Lower age limit** 5 Years

#### Upper age limit

15 Years

#### **Sex** Both

**Target number of participants** 100

#### 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)

Sponsor details Karl-Morre-Gasse 10 Liebnitz Austria 8430 joh.kurz@utanet.at

**Sponsor type** Charity

### Funder(s)

Funder type Charity

Funder Name

## **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