

The effectiveness of camel milk in autism spectrum disorders

Submission date 07/10/2010	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 12/04/2011	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 18/04/2011	Condition category Mental and Behavioural Disorders	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

2011-2

Study information

Scientific Title

The therapeutic possibilities of camel milk in autism spectrum disorders: a longitudinal interventional single-blinded single centre trial

Study objectives

1. To investigate the benefits and effect of camel milk as an interventional strategy in autistic children
2. To determine the efficiency of camel milk as an intervention method in reducing food allergy symptoms seen in autistic children (diarrhoea, vomiting, skin rashes, etc.)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board approved on 23rd March 2011 (ref: 11/2967/IRB)

Primary study design

Interventional

Study design

Longitudinal interventional single-blinded single centre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Autism spectrum disorders

Interventions

This project will be conducted on autistic children (60) with typical behavioural disorders (divided into 2 groups, group 1 will receive cold pasteurised camel milk, group 2 will receive boiled camel milk).

The children will be assessed by a psychologist and a physician who are expert in autism diagnosis. Written informed consent will be obtained from the parents of the children. We will study autistic children with typical behaviour who did not benefit from conventional treatment. A blood sample will be taken (EDTA and plain tubes).

Camel milk will be obtained by the Autism Research and Treatment Centre from a source that will be hygienic and the milk will be tested for bacterial and viral contamination before dispensing to the children. The parents will be instructed not to heat the milk, which would destroy the immunoglobulins and protective proteins therein.

The parents will report daily on the progress of their children. Milk will be supplied frozen and thawed as needed (without adverse effects on the milk, which returns to its initial solution). The milk will replace all other foods for 2 weeks, after which other food can be gradually added to the diet as chosen by the parents.

Resulting information will be used as a tool for the treatment of autism spectrum disorder which would be validated by large-scale clinical trials.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Camel milk

Primary outcome(s)

1. Less allergy
2. Increased attention
3. Increased concentration

Outcomes assessed at baseline, 3 and 6 months, using the following tools:

1. Parent Questionnaire
2. Social Responsiveness Scale (SRS)
3. Childhood Autism Rating Scale (CARS)
4. Autism Treatment Evaluation Checklist (ATEC)

Key secondary outcome(s)

1. Improve general health
2. Improve social relation
3. Improve academic performance

Outcomes measures immediately following intervention, and 3 and 6 months afterwards.

Completion date

10/01/2013

Eligibility

Key inclusion criteria

1. Children with autism spectrum disorders (ASD) confirmed by Autism Diagnostic Observation Schedule (ADOS) and Developmental, Dimensional and Diagnostic Interview (3DI)
2. Aged between 4 and 15 years, either sex
3. All simplex cases

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 Years

Upper age limit

15 Years

Sex

All

Key exclusion criteria

1. Fragile X gene study
2. Tuberous sclerosis
3. Angleman syndrome
4. Other serious neurological conditions (e.g., seizures)
5. Psychiatric (e.g., bipolar disorder) or known medical conditions

Date of first enrolment

10/01/2011

Date of final enrolment

10/01/2013

Locations**Countries of recruitment**

Saudi Arabia

Study participating centre

Autism Research and Treatment Centre

Riyadh

Saudi Arabia

11461

Sponsor information**Organisation**

King Abdul Aziz City for Science and Technology (KACST) (Saudi Arabia)

ROR

<https://ror.org/05tdz6m39>

Funder(s)**Funder type**

Research organisation

Funder Name

King Abdul Aziz City for Science and Technology (KACST) (Saudi Arabia) - Autism Research and Treatment Centre (ART Centre)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes