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The effectivness of camel milk in autism spectrum disorders

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.twahud.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Longitudinal interventional single-blinded single centre trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Professor Al-Ayadhi [ayadh2@gmail.com] to request a patient information sheet

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 measure
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)

Secondary outcome measures
1. Improve general health
2. Improve social relation
3. Improve academic performance

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

Overall study start date
10/01/2011

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

Age group
Child

Lower age limit
4 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
60

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)

Sponsor details
Autism Research and Treatment Centre
Sheikh Al-Amoudi Autism Research Chair
Department of Physiology (29)
Faculty of Medicine
King Saud University
PO Box 2925
Riyadh
Saudi Arabia
11461

Sponsor type
Research organisation

Website
http://twahud.com

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

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