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Exploratory study of a ketogenic dietary supplement in dementia

Submission date
10/10/2013

Recruitment status
No longer recruiting

Registration date
05/11/2013

Overall study status
Completed

Last Edited
30/09/2016

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The aims of this study are to examine the safety and tolerability of a ketone monoester in dementia, and to gather initial data on its effect on cognitive (thought) and motor (movement) function. The ketone monoester is rapidly broken down into a form which neurones (nerve cells) can use instead of glucose.

Who can participate?
Patients with moderate or severe dementia are eligible if they have a caregiver who can give good information about their behaviour and functioning.

What does the study involve?
All 24 patients will take the ketone monoester three times daily for a week. The first and last dose will be taken in the clinic and after cognitive and motor testing.

What are the possible benefits and risks of participating?
There are unlikely to be direct benefits from participation in a short one-week study.
Young healthy volunteers who took the product at substantially higher doses and in different formulations than in this study experienced some side effects like nausea, bloating and dizziness.

Where is the study run from?
The study is running in Oxford and Northamptonshire (UK).

When is the study starting and how long is it expected to run for?
It is anticipated that the study will start in October 2013 and is expected to run until March 2014.

Who is funding the study?
University of Oxford, UK.

Who is the main contact?
Dr Rupert McShane
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Contact information

Type(s)
Scientific

Contact name
Dr Rupert McShane

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v1.1

Study information

Scientific Title
Exploratory study of a ketogenic dietary supplement in dementia: a phase 1 pharmacokinetic and safety study

Acronym
KETOCOG-01

Study objectives
That a ketone monoester drink will be tolerated; converted to safe levels of ketones; and not cause adverse events when taken three times daily for a week.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Wales Research Ethics Committee, 20/09/2013, ref: 13/WA/0267

Study design
Two centres phase 1 before-and-after case series

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Dementia

Interventions
All participants will receive oral 25g D-β-hydroxybutyrate-R 1,3 butanediol three times daily for a week. There are no control groups.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ketone monoesters

Primary outcome measure
1. Ketone levels
2. Adverse events
3. Tolerability
4. Change in Severe Impairment Battery (SIB) at 8 days
5. Clinician Interview Based Impression of Change (CIBIC+)

Measured at baseline and one week only

Secondary outcome measures
1. Change in Alzheimers Disease Cooperative Study - Activities of Daily Living scale at 8 days
2. Change in Neuropsychiatric Inventory carer distress version (NPI) at 8 days
3. Change in Quality of Life measures at 8 days
4. Acute changes in cognitive tests: digit span, Executive Clock Drawing Task (CLOX), semantic fluency
5. Acute changes in fine and gross motor function: Peg Board, Get Up and Go

Measured at baseline and one week only

Overall study start date
21/10/2013

Completion date
31/03/2014

Eligibility

Key inclusion criteria
1. Male or female, age over 70 years old
2. Has moderate or severe dementia
3. Able to walk 10 yards securely

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Established stroke with residual weakness
2. English not first language
3. Unstable medical condition
4. Type 1 Diabetes mellitus

Date of first enrolment
21/10/2013

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Warneford Hospital
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
c/o Heather House
Clinical Trials and Research Governance Joint Research Office
Block 60
Churchill Hospital
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OX3 7LE

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
University/education

Funder Name
University of Oxford

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No