

Exploratory study of a ketogenic dietary supplement in dementia

Submission date 10/10/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/11/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 30/09/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
rupert.mcshane@oxfordhealth.nhs.uk

Contact information

Type(s)

Scientific

Contact name

Dr Rupert McShane

Contact details

Warneford Hospital

Oxford

United Kingdom

OX3 7JX

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rupert.mcshane@oxfordhealth.nhs.uk

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
Oxford
England
United Kingdom
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