

# Exploratory study of a ketogenic dietary supplement in dementia

<b>Submission date</b> 10/10/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 05/11/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 30/09/2016	<b>Condition category</b> 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](mailto:rupert.mcshane@oxfordhealth.nhs.uk)

# Contact information

## Type(s)

Scientific

## Contact name

Dr Rupert McShane

## Contact details

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# Additional identifiers

## Protocol serial number

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

## Study type(s)

Screening

**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(s)**

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

**Key secondary outcome(s))**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

Warneford Hospital

Oxford

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**Sponsor information****Organisation**

University of Oxford (UK)

**ROR**

<https://ror.org/052gg0110>

**Funder(s)****Funder type**

University/education

**Funder Name**  
University of Oxford

## 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes