# Dapagliflozin energy balance in type 2 diabetes

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
08/07/2015		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
08/07/2015	Completed  Condition category	☐ Results		
Last Edited		Individual participant data		
08/02/2019	Nutritional, Metabolic, Endocrine	<ul><li>Record updated in last year</li></ul>		

# Plain English summary of protocol

Plain English summary under review

# Contact information

# Type(s)

Scientific

#### Contact name

Ms Julie Perry

#### Contact details

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# Additional identifiers

Clinical Trials Information System (CTIS)

2013-004264-60

Protocol serial number

19156

# Study information

#### Scientific Title

Compensatory changes in energy balance during dapagliflozin treatment in type 2 diabetes

#### **Acronym**

#### **ENERGIZE**

## **Study objectives**

This study is designed to study the mechanisms underlying the changes in energy balance that occur with dapagliflozin treatment for type 2 diabetes (T2DM), so that in the future it might be possible to develop interventions to optimise weight loss and therefore therapeutic benefit of this agent.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

First MREC approval date 09/06/2014, ref: 14/NW/0340

## Study design

Randomised; Interventional; Design type: Treatment

## Primary study design

Interventional

# Study type(s)

**Treatment** 

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

Topic: Diabetes; Subtopic: Type 2; Disease: Diabetic Control, Metabolic, Nutrition, Obesity

#### **Interventions**

- 1. Dapagliflozin 10mg /day or matching placebo administered orally (double-blind) crossover design
- 2. Short-term (2 x 7 day periods) evaluation
- 3. Long-term (2 x 12 weeks periods) evaluation
- 4. 26 weeks treatment in total)
- 5. Study Entry: Single Randomisation only

## Intervention Type

Drug

#### Phase

Phase IV

# Drug/device/biological/vaccine name(s)

Dapagliflozin

#### Primary outcome(s)

To evaluate the effect of dapagliflozin 10mg daily compared to placebo

#### Key secondary outcome(s))

N/A

#### Completion date

# **Eligibility**

#### Key inclusion criteria

- 1. Type 2 diabetes, either treated with diet alone or up to 2 other oral agents (excluding pioglitazone) with an HbA1c > 7.5% (58mmol/mol) and <11% (97 mmol/mol)
- 2. BMI 20-50kg/m2
- 3. Men and women, Age 18-75

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

75 years

#### Sex

All

### Key exclusion criteria

- 1. Medical History and Concurrent Diseases:
- 1.1. Type 1 diabetes mellitus
- 1.2. History of diabetic ketoacidosis or hyperosmolar nonketotic coma
- 1.3. Hyperthyroidism
- 1.4. Hypothyroidism (subjects with a normal TSH and free T4, and on a stable dose of thyroxine for at least 3 months may be included)
- 1.5. Uncontrolled hypertension (blood pressure >150/90 mmHg)
- 1.6. Recent (< 6 months) myocardial infarction
- 1.7. Previous stroke
- 1.8. Significant cardiac dysrhythmias (including pacemaker or ICD)
- 1.9. Known chronic liver disease (other than hepatic steatosis)
- 1.10. Familial renal glycosuria
- 1.11. History of seizures or unexplained syncope
- 1.12. Pregnancy
- 1.13. Recent major change in body weight (> 3kg loss or gain in preceding month)
- 1.14. Patients with very low BMI (<20kg/m2)
- 1.15. History of malignancy
- 1.16. Presence of any other medical condition that would, in the opinion of the investigator preclude safe participation in the study
- 1.17. Alcohol consumption in excess of daily recommended limits (14 units/week females, 21 units/week males)

- 1.18. Any history of internal metal, pacemakers, or ferromagnetic metallic implants intraocular foreign bodies or cerebral aneurysm clips (exclusion from MR scanning)
- 2. Physical and Laboratory Test Findings:
- 2.1. ALT > 3 x ULN
- 2.2. AST > 3 x ULN
- 2.3. Bilirubin > 2 x ULN
- 2.4. Haemoglobin = 10.5 g/dL (= 105 g/L) for men; haemoglobin = 9.5 g/dL (= 95 g/L) for women
- 2.5. eGFR <60 ml /min
- 2.6. Unexplained haematuria
- 2.7. Weight > 150kg (due to limitations of MRI scanner)
- 3. Allergies and Adverse Drug Reactions:
- 3.1. Subjects with a history of any serious hypersensitivity reaction to dapagliflozin or SGLT-2 inhibitor
- 3.2. Subjects who are allergic or intolerant to any of the study foods in accordance with the Screening questionnaire
- 4. Sex and Reproductive Status see below:
- 4.1. WOCBP who are unwilling or unable to use an acceptable method to avoid pregnancy for the study duration plus 8 weeks
- 4.2. Women who are pregnant or breastfeeding
- 4.3. Sexually active fertile men not using effective birth control if their partners are WOCBP
- 5. Prohibited Treatments and/or Therapies:
- 5.1. Diabetes treated with pioglitazone, GLP-1 analogues or insulin or any other SGLT-2 inhibitor
- 5.2. Use of other weight loss medication or any drug that might affect body weight or appetite (including anti-depressants, antipsychotics, corticosteroids)
- 5.3. Patients who are receiving dapagliflozin
- 5.4. Patients who have participated in a SGLT2 clinical trial within the past 30 days.
- 5.5. Patients who are currently receiving a loop diuretic
- 6. Other Exclusion Criteria:
- 6.1. Prisoners or subjects who are involuntarily incarcerated.
- 6.2. Subjects who are compulsorily detained for treatment of either a psychiatric or physical (e.g. infectious disease) illness.

Eligibility criteria for this study have been carefully considered to ensure the safety of the study subjects and to ensure that the results of the study can be used. It is imperative that subjects fully meet all eligibility criteria.

#### Date of first enrolment

03/08/2015

#### Date of final enrolment

31/12/2016

# Locations

#### Countries of recruitment

United Kingdom

England

#### Cancer Research UK

Liverpool CR-UK Centre - Waterhouse Building 1-3 Brownlow Street Liverpool United Kingdom L69 3GL

# Sponsor information

# Organisation

University of Liverpool

#### **ROR**

https://ror.org/04xs57h96

# Funder(s)

## Funder type

Industry

### **Funder Name**

AstraZeneca

#### Alternative Name(s)

AstraZeneca PLC, Pearl Therapeutics, AZ

### Funding Body Type

Government organisation

#### **Funding Body Subtype**

For-profit companies (industry)

#### Location

**United Kingdom** 

# **Results and Publications**

Individual participant data (IPD) sharing plan

IPD sharing plan summary

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	27/01/2017		Yes	No
HRA research summary			28/06/2023		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes