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Dapagliflozin energy balance in type 2 diabetes

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

Plain English summary of protocol
Plain English summary under review

Contact information

Type(s)
Scientific

Contact name
Ms Julie Perry

Contact details
Cancer Research UK
Liverpool CR-UK Centre - Waterhouse Building
1-3 Brownlow Street
Liverpool
United Kingdom
L69 3GL

Additional identifiers

EudraCT/CTIS number
2013-004264-60

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Secondary outcome measures
N/A

Overall study start date
30/06/2015

Completion date
31/05/2019

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
Planned Sample Size: 52; UK Sample Size: 52; Description: primary outcome measure is energy intake(g) after 12weeks.52 subjects are required in order to detect a 12.5% change with 80% power and at a two-sided 5% level of significance using the method for a paired t-test.This estimate assumes a correlation between measurements of 0.7 and a between-subject standard deviation of 165.The change in energy intake of 12.5% is based on a baseline level of 460g.This allows for a drop-out rate of 20% and was calculated using PROC POWER in SAS 9.3

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
England

United Kingdom

Study participating centre
Cancer Research UK
Liverpool CR-UK Centre - Waterhouse Building
1-3 Brownlow Street
Liverpool
United Kingdom
L69 3GL

Sponsor information

Organisation
University of Liverpool

Sponsor details
Whelan Building, Quadrangle, Brownlow Hill,
Liverpool
United Kingdom
-

Sponsor type
University/education

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

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?
Protocol article	protocol	27/01/2017		Yes	No
HRA research summary			28/06/2023	No	No