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A designer sugar, KarboLyn®, leads to tighter sugar control than glucose in a pre-diabetic cohort

Submission date
16/11/2016

Recruitment status
No longer recruiting

Registration date
22/11/2016

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a growing problem worldwide. People with T2DM have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). Prediabetes is a condition where a person's blood sugar levels are higher than normal, but nor high enough to be classified as T2DM. If left untreated, then prediabetes can turn into T2DM. In people with T2DM and diabetes, when sugar is consumed it causes blood sugar levels to rise as there is not enough insulin (or the insulin is ineffective) to store the sugar for when it's needed later. KarboLyn® is a designer sugar originally developed for athletes interested in carbohydrate loading (a technique used to maximize storage of energy for exercise). It has been shown to be quickly stored in the body without the ending 'crash' that often accompanies these energy bursts. The aim of this study is to look at the way KarboLyn® is broken down and stored in healthy volunteers and those with prediabetes and T2DM compared to glucose.

Who can participate?
In part one, healthy volunteers and those with prediabetes aged 21 or over can take part.
In part two, diabetics aged 21 or over can take part.

What does the study involve?
In part one, participants are asked to fast for eight hours before the study visit and are randomly allocated to one of two groups. Those in the first group consume 50g KarboLyn® and those in the second group consume 50g glucose (sugar). All participants are then asked to walk on a treadmill for two hours. At the start of the study and then 15, 30, 45, 60, 75, 90, 105, and 120 minutes after consuming the sugar, participants stop and have a blood sample taken which is used to measure blood sugar levels.
In part two, participants are asked to fast for eight hours before the study visit and not to take their diabetes medication. At the study visit, all participants consume 10g KarboLyn® and are then asked to walk on a treadmill for two hours. At the start of the study and then 15, 30, 45, 60, 75, 90, 105, and 120 minutes after consuming the sugar, participants stop and have a blood

sample taken which is used to measure blood sugar levels. One week later, participants return for a second study visit which is exactly the same except they consume 10g glucose instead.

What are the possible benefits and risks of participating?
There are no direct benefits involved with participating. There is a small chance of pain or discomfort when blood samples are taken. In part two, diabetic patients may experience a spike in blood sugar which may make them feel unwell.

Where is the study run from?
Montana Medical Research Incorporated (USA)

When is the study starting and how long is it expected to run for?
November 2013 to May 2016

Who is funding the study?
All American Pharmaceutical (USA)

Who is the main contact?
1. Ms Wendy Jones (scientific)
WLJ_1998@yahoo.com
2. Dr Jeff Golini (public)
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
001

Study information

Scientific Title
KarboLyn®, leads to glucose control in a pre-diabetic cohort

Study objectives
The aim of this study is to observe the effect of KarboLyn® Vs glucose has on blood sugar response in normal, pre-diabetic, and Type 2 non-insulin dependent diabetic volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Part 1: Quorum Review IRB Board, 07/01/2014, ref: 29443/1
Part 2: Integ-review Board, 13/05/2015, ref: KL003

Study design
Part 1: Randomised controlled trial
Part 2: Non-randomised study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)

Other

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
Diabetes

Interventions
Part 1:
After an 8-hour fast (minumum), normal and pre-diabetic volunteers are randomized to one of two groups.

Group 1: Participants receive 50g KarboLyn®
Group 2: Participants receive 50g glucose

Following consumption of the study sugar, participants are asked to walk on a treadmill (~1mph) for a period of 2 hours. At baseline, 15 minutes, 30 minutes, 45 minutes, 60 minutes, 75 minutes, 90 minutes, 105 minutes, and 120 minutes, participants stop and have blood samples drawn in order to measure blood glucose levels.

Part 2:
All diabetic volunteers are withdrawn from their oral diabetic medication for one cycle and fast for a minimum of 8 hours prior to commencement of the study. All participants receive KarboLyn® (10 grams) and are then asked to walk on a treadmill (~1mph) for a period of 2 hours. At baseline, 15 minutes, 30 minutes, 45 minutes, 60 minutes, 75 minutes, 90 minutes, 105 minutes, and 120 minutes, participants stop and have blood samples drawn in order to measure blood glucose levels.
After one week ‘off’, the same volunteers are treated in the above manner prior to receiving 10 grams of glucose. Blood draw conditions and timing are the same.

Intervention Type
Not Specified

Primary outcome measure
Blood sugar is measured by blood draws and standard glucose testing at ‘0’ (before consumption), and at 15 minutes, 30 minutes, 45 minutes, 60 minutes, 75 minutes, 90 minutes, 105 minutes, and 120 minutes for all volunteers.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2013

Completion date
13/05/2016

Eligibility

Key inclusion criteria
Part 1:
Healthy volunteers:
1. Aged 21 years and over
2. Healthy (not a pre-diabetic or diabetic)
3. Normal blood sugar level (fasting glucose is less than or equal to 100 mg/dl)

Pre-diabetics:
1. Aged 21 years and over
2. Pre-diabetic not currently taking any diabetic related medication to control blood sugar level
3. Fasting blood sugar is greater than 100 mg/dl and less than 130 mg/dl

Part 2:
1. Aged 21 years and over
2. Diabetic (fasting blood sugar is between 125 mg/dl and 200 mg/dl)

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Normal controls: 24 / pre-diabetics: 12 / Type 2 diabetics: 6

Key exclusion criteria
Parts 1 and 2:
1. Pregnancy
2. Heath condition making participant unable to walk on a treadmill for 2 hours

Date of first enrolment
01/07/2014

Date of final enrolment
21/12/2015

Locations

Countries of recruitment
United States of America

Study participating centre
Montana Medical Research Incorporated
2683 Palmer St, Ste B

Missoula
United States of America
59808

Sponsor information

Organisation
All American Pharmaceutical

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Sponsor type
Industry

ROR
https://ror.org/03x3d2a47

Funder(s)

Funder type
Industry

Funder Name
All American Pharmaceutical

Results and Publications

Publication and dissemination plan
Planned publication in the Journal of Diabetes and Metabolic Disorders.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Wendy Lou Jones, MSc (WLJ_1998@yahoo.com) and Dr. Jeff Golini, PhD (drjeff@allamericanpharmaceutical.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2017	24/01/2019	Yes	No