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Comparison of the effects of a low carbohydrate diet versus a diet upon the recommendations of the clinical practice guideline (high-carb, low-fat) in the treatment of type 2 diabetes

Submission date
12/09/2011

Recruitment status
No longer recruiting

Registration date
19/09/2011

Overall study status
Completed

Last Edited
07/01/2014

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Recent research has raised questions about the appropriate diet-related treatment (dietetic treatment) of type 2 diabetes, where controlling blood sugar levels (glycemic control) is a vital part of therapy. The current dietetic strategy, established in clinical practice guidelines, recommends a diet high in carbohydrates and low in fat and protein. In contrast, a nutrition low in carbohydrates with higher amounts of fat and protein has also been associated with better glycemic control in diabetics. This study aims to compare the glycemic effects of both diets and hence supports the evaluation of dietetic treatment options for diabetes.

Who can participate?
Inpatients of the rehab clinic in North Rhine-Westphalia, Germany, who have type 2 diabetes, and are aged 18 years or above.

What does the study involve?
Participants will be randomly allocated to consume either a diet high in carbohydrates and low in fat and protein, or a diet low in carbohydrates with higher amounts of fat and protein. During the three-week inpatient rehabilitation, participants will receive all meals of the day according to their assigned diet plan. After completion of the rehabilitation participants should continue with their diet plan for another 21 weeks. Participants are then invited to the rehab clinic for a final examination. Participants will receive physical check-ups and complete questionnaires at the beginning and the end of the rehabilitation and 24 weeks after the start of the study.

What are the possible benefits and risks of participating?
Participants may see an improvement in their health and physical function. There are no known risks associated with taking part in this study.

Where is the study run from?
University of Witten/Herdecke, Germany.

When is the study starting and how long is it expected to run for?
Enrolment of participants began in March 2011 and ended in October 2013. Follow-up examinations will continue until May 2014.

Who is funding the study?
Association for the Advancement of Rehabilitation Research, Norderney, Germany.

Who is the main contact?
Jan Karoff
jkaroff@rehaforschung-koenigsfeld.de

Contact information

Type(s)
Scientific

Contact name
Mr Jan Karoff

Contact details
Universität Witten/Herdecke
Office:
Holthauser Talstraße 2
Ennepetal
Germany
58256
+49 (0)2333 9888 484
jkaroff@rehaforschung-koenigsfeld.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Low carbohydrate nutrition in the treatment of type 2 diabetes: A randomized controlled trial on the glycemic effects of a low carbohydrate diet in comparison to a diet upon the recommendations of the clinical practice guideline (high-carb, low-fat)

Acronym
DIKE

Study objectives
DIKE (Diabetes-Intervention mit kohlenhydratreduzierter Ernährung). A diet low in carbohydrates - in comparison to a (high-carb, low-fat) diet according to the clinical practice guideline - leads to improved diabetes control i.e. more favorable blood glucose values, namely HbA1c and fasting blood glucose.

On 03/01/2014 the anticipated end date was changed from 31/12/2013 to 30/06/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the University Witten/Herdecke (Ethik-Kommission der Universität Witten /Herdecke e. V.), 25/01/2011, ref: 98/2010

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
1. Written consent of patient is required for participation in the trial. The potential study population recruits itself from the group of newly arrived inpatients of a German rehab hospital (indications: cardiology, orthopedic).
2. Baseline: data allocation for measurement time point 1 (t1).
3. Randomization to the two study arms followed by dietetic intervention: Whilst their three-week inpatient-rehabilitation, the study participants receive all meals of the day according to their assigned diet-plan. Nutrition in test group / control group: 25/55% carbohydrates, 30/15% protein, 45/30% fat.
4. During their rehabilitation, study participants experience theoretical lessons and a practical training in nutrition according to their diet-plan.

5. Week 3: Data allocation for measurement time point 2 (t2).
6. After completion of the rehabilitation, study participants are intended to stick to their diet-plan for another 21 weeks.
7. Three-day dietary records are administered in week 16 of the trial. Individual feedback by a nutritionist is provided to the participants.
8. After 24 weeks participants are invited to the rehab hospital for the trials final examination.
9. Week 24: Data allocation for measurement time point 3 (t3).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Blood glucose parameters:
1.1. HbA1c
1.2. Fasting blood glucose
Measured at t1: baseline, t2: after 3 weeks, t3: after 24 weeks

Secondary outcome measures
Surrogate markers:
1. Insulin level
2. Homeostasis Model of Assessment - Insulin Resistance (HOMA-IR)
3. Creatinine
4. Glomerular filtration rate
5. Body weight
6. Body-mass-index
7. Waist circumference
8. Serum lipid levels [total-, high density lipoprotein (HDL)-, low density lipoprotein (LDL)-cholesterol, triglyceride]

Survey data:
1. Diabetes-medication (type and dose rate)
2. Diabetes treatment satisfaction (DTSQs/DTSQc)
3. Satisfaction with the diet (self constructed)
4. Quality of life (WHO-5)
5. Physical activity* (inpatient rehab data [t2], Freiburger Fragebogen zur körperlichen Aktivität [t3])

*Note: No measurement at time point 1 [t1] due to reduction of activities in rehab-inpatients affected by cardiac or orthopedic events.

Overall study start date
22/03/2011

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Newly arrived inpatient of a selected rehab clinic (indications: cardiology, orthopedic) in North Rhine-Westphalia, Germany
2. Pre-diagnosed type 2 diabetes
3. Age of 18 years and above, either sex
4. Written consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1 test group (82 participants), 1 control group (82 participants). Total: 164 participants.

Key exclusion criteria
1. No type 2 diabetes
2. Renal insufficiency (creatinine of 2.5 mg/dl and above)
3. Pregnancy
4. Consuming disease
5. Rudimental / poor literacy (German)

Date of first enrolment
22/03/2011

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
Germany

Study participating centre
Universität Witten/Herdecke
Ennepetal
Germany
58256

Sponsor information

Organisation
Association for the Advancement of Rehabilitation Research, Norderney (Germany)

Sponsor details
Verein zur Förderung der Rehabilitationsforschung e.V. Norderney
Kaiserstraße 26
Norderney
Germany
26548

Sponsor type
Government

Website
http://www.rehaforschung-norderney.de

Funder(s)

Funder type
Government

Funder Name
Association for the Advancement of Rehabilitation Research, Norderney (Verein zur Förderung der Rehabilitationsforschung e.V. Norderney) (Germany)

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