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The effect of an experimental prune-based nutritional supplement for reducing the body mass index in moderately overweight women

Submission date
18/07/2012

Recruitment status
Stopped

Registration date
02/08/2012

Overall study status
Stopped

Last Edited
18/01/2019

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
In overweight individuals reducing weight prevents or improves common chronic diseases like diabetes (high blood sugar) and arterial hypertension (increased blood pressure). The aim of this study is to evaluate whether a prune-based nutritional supplement which enhances the feeling of satiety (feeling satisfied) may help in limiting daily food consumption.

Who can participate?
Women >18 years of age without severe comorbidity and a body mass index (BMI) between ≥25 and <35. We will exclude pregnant or breast-feeding women, women with a known allergy to prunes and / or endocrine disorders (i.e., hyper- or hypothyroidism, known diseases of the ovary, the adrenal or pituitary glands).

What does the study involve?
Participants will randomly be assigned to daily intake of 40 g of a prune-base nutritional supplement (PDF4 gel), or an undistiguishable placebo (dummy) for two weeks. The protocol allows for an otherwise unrestricted diet. Clinical assessments including measurement of height and weight will be made at baseline (i.e., before allocation to one or the other intervention), after two and four weeks. Participants will be asked to fill out standardized health outcome form and a questionnaire about eating habits at baseline and after two weeks.

What are the possible benefits and risks of participating?
According to German regulations, the investigators are obliged to inform potential participants that they cannot guarantee any benefit from trial participation. The prune formulation may ease weight reduction by avoiding the feeling of hunger. Both the PDF4 gel and the placebo gel have been classified as nutritional supplements according to German federal and European laws. We do not expect specific risks for the trial participants.

Where is the study run from?
Participants will be recruited at the Spa Health Resort in Bad Ems, Germany.

When is the study starting and how long is it expected to run for?
This is a pilot trial to be commenced in August 2012. The expected recruitment period is four months. In case of a faster than forecasted enrollment, the trial will be closed after inclusion of the required 60 participants.

Who is funding the study?
The study is funded by the manufacturer, Dynamic Nutrition Lab, Miesbach, Germany, and QinDAO Research & Development, Berlin, Germany.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CIP MPMG-2012-03_013

Study information

Scientific Title
Short-term effectiveness of prunus domestica containing a nutritional supplement (PDF4) in reducing weight and improving health-related quality of life in women with pre-obesity and grade I obesity (Body Mass Index 25 kg/m2 to 35 kg/m2): A placebo-controlled, randomized pilot trial

Study objectives

In women with pre-obesity and obesity grade I, nutritional supplementation with PDF4 gel will lead to an average reduction in BMI of 1.5 - 2.0 kg/m2 two weeks after randomization compared to a placebo control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Commission Freiburg, Germany, 16 July 2012, ref: FEKI 012 / 1546

Study design
Placebo-controlled randomized single-center trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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
Moderately overweight

Interventions
Experimental treatment: nutritional supplement PDF4 gel 40g/d for two weeks (containing prunus domestica extract) + normal food intake

Control: placebo gel 40g/d for two weeks + normal food intake

Both interventions have been classified as a nutritional supplements complying with German Federal and European regulations.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Mean difference in BMI reduction between verum (PDF4 gel) and placebo gel two weeks after randomization

Secondary outcome measures
1. The average reduction in BMI four weeks after randomization, and the difference between verum and placebo
2. The change in health-related quality of life as assessed by the Short Form 8 (SF-8) questionnaire, its physical and mental component scores, and the difference to population norms two weeks after randomization
3. To assess the effect of the verum and placebo intervention on specific eating habits.

Overall study start date
01/08/2012

Completion date
01/11/2012

Eligibility

Key inclusion criteria
1. Otherwise healthy women [American Society of Anesthesiologists (ASA) grade I / II] >18 years
2. Moderately overweight [i.e. pre-obesity (BMI 25.0 29.9) and grade I obesity (BMI 30.0 34.9)] according to the WHO classification
3. Capable of understanding the nature of a randomized controlled trial
4. Willing to participate and to provide written informed consent
5. Willing to comply with study-specific assessments during follow-up

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
2 x 30 balance block randomization

Key exclusion criteria
1. BMI <25 or BMI >35
2. Pregnancy or lactation
3. Known allergy against any of the ingredients of the verum or placebo gel
4. Known endocrine diseases (e.g. hyper- or hypothyroidism, polycystic ovaries, disorders of the adrenal gland or hypophysis)
5. Enteric disorders and malresorption
6. Psychiatric conditions

Date of first enrolment

01/08/2012

Date of final enrolment
01/11/2012

Locations

Countries of recruitment
Germany

Study participating centre
Alter Postweg 6
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Sponsor information

Organisation
Dynamic Nutrition Lab (Germany)

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Dynamic Nutrition Lab (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