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Treatment of Diabetic Foot with Glutamine Dipeptide

Submission date	Recruitment status	[ ] Prospectively registered
20/11/2014	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/12/2014	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/12/2014	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

People with diabetes are more likely to develop peripheral arterial disease (narrowing of the arteries, which then affects the flow of blood to nearby tissues) and neuropathy (where damage to small blood vessels supplying nerves causes the nerves themselves to become damaged or destroyed). Diabetics are more at risk of developing infections, and developing infections that are harder to treat. They are also vulnerable to severe foot problems, such as diabetic foot. In the worse cases, this can result in gangrene and amputation of the foot. The amino acid glutamine is involved in many functions of the cell. It has antioxidant and anti-inflammatory properties, can protect body tissues and nerves and has been used to boost the immune system. It has also been shown to reduce blood pressure and blood sugar levels. If we take in glutamine orally (by mouth, for example, by taking a pill) we can only absorb about 50% of this amino acid into our body. However, this can be rectified by taking a compound made up of glutamine and another amino acid, alanine, which together make up glutamine dipeptide (GDP). We want to investigate how GDP supplements may affect the metabolism of people with type 2 diabetes (T2DM) and whether it helps in the treatment of diabetic foot.

Who can participate?

Adults aged between 40-70 with T2DM and diabetic foot.

What does the study involve?

The study is in two stages. For the first stage, participants are interviewed using a questionnaire and information about their pharmacotherapeutic profile, lifestyle, age, gender, education, marital status, associated diseases and foot care is collected. After analyzing the data, a final group of participants are selected for the second stage. These patients are given sachets containing GDP to take dissolved in water for 30 days. After the 30 days of treatment, blood samples are taken for analysis to determine the effects of the GDP supplement.

What are the possible benefits and risks of participating?

The benefits include free medical care (including lab tests) and, potentially, improvement in the participants diabetic conidtion. We have not found any side effects of taking GDP.

Where is the study run from?
Maringá State University (Brazil)

When is the study starting and how long is it expected to run for?
March 2013 to September 2013

Who is funding the study?
1. National Council of Scientific and Technological Development (Brazil)
2. Research Program for the Public Health System (Brazil)

Who is the main contact?
Dr Roberto Bazotte

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
09108912.9.0000.0104 - Plataforma Brasil/Sistema Nacional de Ética em Pesquisa

Study information

Scientific Title
Evaluation of the impact of Glutamine Dipeptide Supplementation on metabolic profile and chronic complications associated with Diabetic Foot

Study objectives
Our expectation based on the scientific literature would be an improvement of the pathological conditions of the patients with diabetic foot, evaluated by biochemical, hematological, oxidative, inflammatory parameters and feet sensitivity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Platform Brazil / National System of Ethics, 02/18/2013, ref. COPEP - CAAE 204.758

Study design
Treatment with a single group of patients, prospective, single-centre

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Type two diabetes and diabetic foot complication

Interventions
This is a clinical study where each patient is his own control. This type of study is used to investigate the effectiveness of therapeutic procedures and involves the investigation of the current results of a new treatment, compared with those obtained before treatment.

The selection of patients will be in two stages.

First stage: the patients that meet the inclusion criteria will participate in a lecture where they will receive detailed explanations about this research. Those who agree to participate will give informed consent. Sensitivity of the feet based on the National Hansen's Disease Program (NHPD) developed by the University of Baton Rouge, Louisiana / USA will be tested. Laboratory tests will measure interleukins, C-reactive protein, tumor necrosis factor-alpha (TNF-alfa), total antioxidant capacity, reduced protein thiols, fasting glucose, glycated hemoglobin A1c (HbA1c)

and the correlation of these parameters with inflammatory markers. These initial results will serve as parameters for the final selection of patients and will be treated as initial research data. All patients will be interviewed: gender, age, education, marital status, lifestyle (physical exercise, smoking and drinking), time of diagnosis, medication use, associated diseases and foot care (types of shoes, socks, presence of calluses, tingling, loss of sensation, swelling, nails and interdigital mycosis). Measurements of weight, height, waist and hip circumference will be done.

Second stage: after analyzing the data obtained in the initial phase and respecting the criteria for inclusion and exclusion, the final selection of patients will be performed. Those patients will receive sachets containing glutamine dipeptide for oral administration (20 g / day), during 30 days. Patients will drink the contents of sachets dissolved in water before the main meal. After 30 days of treatment patients the second blood collection will be done for evaluation of biochemical parameters, markers of oxidative stress, inflammatory response and infectious processes.

In the event of any reported side effects (reported by the patient or detected by the laboratory), the patient will be excluded from the protocol.
During the study, procedures will be performed in order to not interfere with the medical treatment of each patient.

Intervention Type
Supplement

Primary outcome measure
Test sensitivity of the feet based on the National Hansen's Disease Program (NHPD) developed by the University of Baton Rouge, Louisiana / USA.
Interleukins, C-reactive protein, tumor necrosis factor-alpha (TNF-alfa), total antioxidant capacity, reduced protein thiols; fasting glucose, glycated hemoglobin A1c (HbA1c) and the correlation of these parameters with inflammatory markers.

Secondary outcome measures
Questions on lifestyle (physical exercise, smoking and drinking), time of diagnosis, medication use, associated diseases and foot care (types of shoes, socks, presence of calluses, tingling, loss of sensation, swelling, nails and interdigital mycosis). Measurements of weight, height, waist and hip circumference will be done.

Overall study start date
01/03/2013

Completion date
30/09/2013

Eligibility

Key inclusion criteria
Patients aged between 40 and 70 with type 2 diabetes and diabetic foot.

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
Severe hypertension and/or hyperlipidemia; previous history of ischemic heart disease; nephropathy, pregnancy or intention to become pregnant during the study period; changes in laboratory evaluation of aspartate amino transferase (AST), alanine amino transferase (ALT) and gamma glutamyl transferase (gamma GT).

Date of first enrolment
01/03/2013

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
Brazil

Study participating centre
Maringá State University
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Sponsor information

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Funder(s)

Funder type
Government

Funder Name
National Council of Scientific and Technological Development- CNPq- Brazil

Funder Name
Research Program for the Public Health System- PPSUS- Brazil

Results and Publications

Publication and dissemination plan
A manuscript has been submitted to Diabetes Care

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration