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Assessing the clinical benefit of food supplement, Genecol®, in subjects with joint pain at the lower, upper limbs or at the lumbar spine

Submission date
01/02/2010

Recruitment status
No longer recruiting

Registration date
22/02/2010

Overall study status
Completed

Last Edited
12/08/2013

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Joint pain is a major cause of disability in subjects aged over 50 years. Symptomatic pain relief can be obtained with painkillers such as paracetamol or non-steroidal anti-inflammatory drugs. These treatments, while generally safe when used at low doses and for a short time, can result in serious complications (gastrointestinal bleeding, kidney failure, coronary heart disease) when used for a long time or at higher doses and could obviously reduce the adherence to treatment. In subjects with joint symptoms, food supplements are often taken by patients with the aim to relieve pain and improve physical function. GENACOL®, a food supplement made of collagen hydrolysate, is a food supplement that claims to improve joint symptoms. The aim of this study is to assess whether taking this food supplement over 24 weeks increases the number of subjects with an improvement in joint pain and/or physical function symptoms.

Who can participate?
Men and women aged over 50 years with joint pain (hip, knee, elbow, shoulder, hand and/or lumbar spine).

What does the study involve?
Subjects were randomly allocated to receive either GENACOL® (three hard gel capsules per day) or a dummy/placebo (identical hard gel capsules, to be consumed in the same daily dosage). The target joint that was followed-up throughout the study was the most painful joint at the first visit. As the product tested is a food supplement, no accurate diagnosis of joint pain was performed.

What are the possible benefits and risks of participating?
A reduction of joint pain is expected in the GENACOL group. No specific risk is expected as this product is already marketed without significant adverse events.

Where is the study run from?
University of Liège (Belgium).

When is the study starting and how long is it expected to run for?
The study started in July 2009 and finished in January 2011.

Who is funding the study?
The study was financed by Nutraveris (France).

Who is the main contact?
Prof Jean-Yves Reginster
jyreginster@ulg.ac.be

Contact information

Type(s)
Scientific

Contact name
Prof Jean-Yves Reginster

Contact details
University of Liège
CHU Sart Tilman Bat B23
Liege
Belgium
4000

Additional identifiers

Protocol serial number
NUTRA-CH-01

Study information

Scientific Title
A randomised, double-blind, placebo-controlled phase IV trial to assess the clinical benefit of Genacol®, a food supplement made of a proprietary collagen hydrolysate (1200 mg/day), over a period of 24 weeks, in subjects with joint pain at the lower, upper limbs or at the lumbar spine

Study objectives
Genacol® is a food supplement made of a proprietary collagen hydrolysate already registered, as food supplement, in various countries, including Belgium, Canada, France, the United Kingdom, Spain, Italy, the United States, and others. The aim of this supplementation is to reduce pain and reduce functional disabilities in subjects with joint pain.

On 12/08/2013, the anticipated end date was changed from 01/07/2010 to 01/01/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of Liege CHU approved on 17/06/2009 (ref: B70720096310)

Primary study design
Interventional

Study design
Randomised double blind placebo controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Joint pain

Interventions
Participants will be randomised to receive
1. Genacol®
Active ingredient: Collagene hydrolysate (400 mg/capsule; 1200 mg/day)
2. Placebo
Main ingredient: maltodextrin (400 mg/capsule; 1200 mg/day)
Participants will be required to take three hard gel capsules once daily before bed during the entire study period (24 weeks)

Intervention Type
Other

Phase
Phase IV

Primary outcome(s)
Percentage of clinical responders between the active treatment and placebo groups

Key secondary outcome(s)
Outcomes will be evaluated at weeks 12 and 24
1. Pain rescue treatment consumption
2. Pain/function changes; assessed by
2.1. Visual analogue scale (VAS)
2.2. Lequesne index
2.3. Disability of Arm Shoulder and Hand (DASH) score
2.4. Functional Disability Scale for the Assessment of Low Back Pain (Echelle d'Incapacité Fonctionnelle pour l'Evaluation des Lombalgies [EIFEL]) questionnaire
3. Health-related quality of life changes; assessed with the SF-36
4. Utility value changes; assessed by EQ-5D
5. Tolerability and incidence of any adverse events
6. Global satisfaction of the treatment will be assessed by mean of a global questionnaire (also at week 4)

Completion date
01/01/2011

Eligibility

Key inclusion criteria
Men and women over 50 years with joint pain (hip, knee, elbow, shoulder, hand and lumbar spine) over 30 mm on a 0-100 mm visual analogue scale.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Unlikely to cooperate in the study
2. Poor compliance anticipated by the investigator
3. Participating in another trial at the same time or within the previous 1 month with active therapeutic intervention (except if the patient only performed the screening visit without taking the tested supplement)

Date of first enrolment
01/07/2009

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
Belgium

Study participating centre
University of Liège
Liege
Belgium
4000

Sponsor information

Organisation
Nutraveris (France)

ROR
https://ror.org/05xc9cz73

Funder(s)

Funder type
Industry

Funder Name
Nutraveris (France)

Results and Publications

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?
Results article	results	01/06/2012		Yes	No