

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

<b>Submission date</b> 01/02/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 22/02/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/08/2013	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> 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**  
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Liege  
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4000

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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)

### **Study design**

Randomised double blind placebo controlled study

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **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**

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 measure**

Percentage of clinical responders between the active treatment and placebo groups

### **Secondary outcome measures**

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)

### **Overall study start date**

01/07/2009

### **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

### **Age group**

Senior

### **Sex**

Both

### **Target number of participants**

200

### **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)

**Sponsor details**

Nutraveris

18 C, rue du Sabot

Ploufragan

France

22440

**Sponsor type**

Industry

**ROR**

<https://ror.org/05xc9cz73>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Nutraveris (France)

# 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2012		Yes	No