

# Influence of drug containing ginger extract on arthritic pain and gastropathy in patients with osteoarthritis

<b>Submission date</b> 07/08/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/11/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/11/2010	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

616-08:612.018;612.4:616.7

## Study information

### Scientific Title

Influence of drug containing ginger extract on arthritic pain and gastropathy in patients with osteoarthritis: a randomised active controlled clinical trial

### **Study objectives**

Traditional non-steroidal anti-inflammatory drugs (NSAIDs) inhibit COX-1,2 expression leading to the lack of prostaglandins (PG). PG play a crucial role in mechanisms of mucosal defense. This drug containing ginger extract inhibits COX-2 and increases PG production in gastric mucosa. It seems to be an alternative to traditional NSAIDs especially in patients with osteoarthritis with risk factors of NSAID-induced gastropathy.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Local Ethics Committee of Central Scientific Research Institute of Gastroenterology approved on the 31st August 2007

### **Study design**

Randomised active controlled clinical trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Osteoarthritis, NSAID-induced gastropathy

### **Interventions**

The patients were randomised in two groups, using methods of envelopes, to:

1. Group ZG (n = 21): ginger and glucosamine combination (Zinaxin Glucosamine: 170 mg ginger extract [Zingiber officinalis, EV.EXT 35] and 500 mg glucosamine, as glucosamine sulphate, per capsule, Ferrosan AS, Denmark) 2 capsules orally daily
2. Group DG (n = 22): diclofenac and glucosamine combination (100 mg diclofenac as sodium diclofenac and 1000 mg glucosamine as glucosamine sulphate) daily

The duration of treatment was 28 days.

### **Intervention Type**

Drug

### **Phase**

Phase IV

### **Drug/device/biological/vaccine name(s)**

Ginger extract, diclofenac

### **Primary outcome(s)**

Upper GI lesions (erosion, ulcer) were assessed on the 28 day of treatment with upper GI endoscopy

**Key secondary outcome(s)**

Gastritis

**Completion date**

01/06/2009

**Eligibility**

**Key inclusion criteria**

1. Aged over 18 years, either sex
2. Osteoarthritis (OA) pain syndrome availability of more than 40 mm according to Visual Analogue Scale (VAS)
3. Requiring anti-inflammatory therapy assignment
4. NSAID-gastropathy or dyspepsia development from NSAID therapy in anamnesis
5. Informed patient consent to administer the preparation
6. Compliance with the listed research protocol

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Ulcer presence during upper gastrointestinal (GI) endoscopy and more than 5 stomach mucosa and/or duodenum erosions, and/or erosive oesophagitis
2. High risk of cardiological complications, arterial hypertension, cardiac insufficiency greater than II degree, myocardial infarction or apoplectic attack in anamnesis during the previous 3 years, chronic kidney disease, liver insufficiency, bronchial asthma, subcompensated or decompensated diabetes mellitus, oncological diseases
3. NSAID administration, aspirin in anti-aggregant doses, glucocorticosteroids
4. Pregnancy

**Date of first enrolment**

01/06/2008

**Date of final enrolment**

01/06/2009

## Locations

### Countries of recruitment

Russian Federation

### Study participating centre

Central Scientific Research Institute of Gastroenterology

Moscow

Russian Federation

111123

## Sponsor information

### Organisation

Central Scientific Research Institute of Gastroenterology (Russia)

## Funder(s)

### Funder type

Research organisation

### Funder Name

Central Scientific Research Institute of Gastroenterology (Russia) - Healthcare Department

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration