

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

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Registration date 26/11/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/11/2010	Condition category 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet (Russian only)

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 measure

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

Secondary outcome measures

Gastritis

Overall study start date

01/06/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40

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

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Sponsor information**Organisation**

Central Scientific Research Institute of Gastroenterology (Russia)

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Sponsor type

Research organisation

Funder(s)

Funder type

Research organisation

Funder Name

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

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