ISRCTN48110500 https://doi.org/10.1186/ISRCTN48110500

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

Submission date	Recruitment status	[ ] Prospectively registered
07/08/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/11/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/11/2010	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Vladimir Drozdov

Contact details
Central Scientific Research Institute of Gastroenterology
Shosse Entuziastov,86
Moscow
Russian Federation
111123
+7 (8)495 304 1942
zvopt@yandex.ru

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
111123

Sponsor information

Organisation
Central Scientific Research Institute of Gastroenterology (Russia)

Sponsor details
c/o Vladimir N. Drozdov
Shosse Entuziastov, 86
Moscow
Russian Federation
111123
+7 (8)495 304 1942
zvopt@yandex.ru

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