ISRCTN18723747 https://doi.org/10.1186/ISRCTN18723747

Influence of ibuprofen-arginine on serum levels of nitric oxide metabolites in patients with chronic lower back pain: a single-blind, placebo-controlled pilot trial

Submission date
16/02/2006

Recruitment status
No longer recruiting

Registration date
17/02/2006

Overall study status
Completed

Last Edited
20/12/2007

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2003DR4004

Study information

Scientific Title

Study objectives
The present study investigates whether ibuprofen-arginine has a cyclooxygenase-independent pain modulating property besides its known anti-inflammatory effect.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local ethics committee (Kantonale Ethics commission Zurich) on the 8th November 2002 (ref: 427).

Primary study design
Interventional

Study design
A single-blind, placebo-controlled pilot trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lower back pain

Interventions
Ibuprofen-arginine 400 mg (verum) was administered orally once.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ibuprofen-arginine 400 mg (verum)

Primary outcome(s)
No metabolites.

Key secondary outcome(s)
Pain intensity (VAS).

Completion date
14/10/2003

Eligibility

Key inclusion criteria
Non-specific chronic lower back pain (Visual Analogue Scale [VAS] greater than or equal to 60).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Specific lower back pain.

Date of first enrolment
04/03/2003

Date of final enrolment
14/10/2003

Locations

Countries of recruitment
Switzerland

Study participating centre
Department of Rheumatology
Zurich
Switzerland
CH-8091

Sponsor information

Organisation
Zambon Svizzera S.A. (Switzerland)

ROR
https://ror.org/04zrd1t35

Funder(s)

Funder type
Industry

Funder Name
Zambon Svizzera S.A. (Switzerland)

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	01/12/2006		Yes	No