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

Contact name
Dr Haiko Sprott

Contact details
Department of Rheumatology
Institute of Medical Research
University Hospital of Zurich
Gloriastrasse 25
Zurich
Switzerland
CH-8091
+41 (0)44 255 3010
haiko.sprott@usz.ch

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
No metabolites.

Secondary outcome measures
Pain intensity (VAS).

Overall study start date
04/03/2003

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

Age group
Adult

Sex
Both

Target number of participants
20

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)

Sponsor details
Via Industria 13
Casella postale 200
Cadempino
Switzerland
CH-6814
+41 (0)91 960 4118
Ralf.Ruffmann@zambongroup.com

Sponsor type
Industry

Website
http://www.inpharzam.ch/

ROR
https://ror.org/04zrd1t35

Funder(s)

Funder type
Industry

Funder Name
Zambon Svizzera S.A. (Switzerland)

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?
Results article	Results	01/12/2006		Yes	No