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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
16/02/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/02/2006	Completed	[X] Results		
<b>Last Edited</b> 20/12/2007	Condition category Injury, Occupational Diseases, Poisoning	[] Individual participant data		

#### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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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).

#### Study design

A single-blind, placebo-controlled pilot trial

#### Primary study design

Interventional

#### 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