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# Cyclo-oxygenase inhibition and muscular function in hospitalised geriatric patients with inflammation

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|---|---|---|
| **Submission date**<br>07/04/2011 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>28/04/2011 | **Overall study status**<br>Completed | |
| **Last Edited**<br>31/08/2012 | **Condition category**<br>Other | |

**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**
N/A

## Study information

**Scientific Title**

NSAID treatment with piroxicam versus placebo in hospitalised geriatric patients with infection-induced inflammation - influence on muscle function: a single centre double blind randomised controlled trial

## Study objectives
The treatment with a non steroidal anti-inflammatory drug (NSAID) in addition to standard antibiotic therapy might attenuate infection-induced inflammation and reduce its negative effects on muscle function

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Hospital ethics committee (Comité d'éthique hospitalier), CHU Brugmann approved on 17/12 /2004 and amendements approved on 19/05/2005 (N/Ref CE 2004/44)

## Study design
Single centre double blind randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Infection-induced inflammation and related muscle weakness

## Interventions
10 mg piroxicam daily versus placebo in addition to standard care including antibiotics

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
1. Skeletal muscle mass (total body potassium) evaluated at baseline & weekly thereafter maximum two times
2. Muscle performance (grip strength, fatigue resistance and Elderly Mobility Scale (EMS) score evaluated at baseline & weekly thereafter with a maximum of three weeks
3. Inflammation (levels of cytokines and heat shock proteins) evaluated at baseline, daily during the first 3 days and weekly after baseline with a maximum of three weeks

## Key secondary outcome(s))
1. Clinical evolution evaluated at discharge
2. Length of stay
3. Tolerance and adverse events evaluated daily throughout hospitalisation

## Completion date

30/04/2006

# Eligibility

### Key inclusion criteria
1. Patients hospitalised in an acute geriatric ward
2. Age > 70 years
3. Inflammation, not due to surgery or burns, and documented by an increase of serum concentration of C-reactive protein (CRP) (> 10 mg/L) and/or fibrinogen (>400 mg/dL)
4. Informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Senior

### Sex
All

### Key exclusion criteria
1. General condition, dementia or confusion, not allowing the testing
2. Patients in (pre) terminal phase
3. Use of corticosteroids or non -steroidal anti-inflammatory drugs (NSAIDs) in the past 7 days; the use of inhalation corticosteroids, of low dose aspirin (as anti-aggregating medication) or of paracetamol is allowed
4. Contra-indication for the use of cyclo-oxygenase (COX)-2 inhibitors

### Date of first enrolment
01/05/2005

### Date of final enrolment
30/04/2006

# Locations

### Countries of recruitment
Belgium

### Study participating centre
**Geriatric Department**
Brussels
Belgium
1090

# Sponsor information

### Organisation
Brussels University Hospital (Belgium) (Universitair Ziekenhuis Brussel)

### ROR
https://ror.org/038f7y939

# Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Brussels University Hospital (Belgium)-Scientific Willy Gepts Fund ("Wetenschappelijk Fonds Willy Gepts" of the Universitair Ziekenhuis Brussel)

### Funder Name
Brugmann University Hospital Brussels Centre (Belgium) (Centre Hospitalier Universitaire Brugmann and Universitair Ziekenhuis Brussel, Brussels)

# 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 | 01/03/2012 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |