

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

Submission date 07/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/04/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 31/08/2012	Condition category Other	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

1. Clinical evolution evaluated at discharge
2. Length of stay
3. Tolerance and adverse events evaluated daily throughout hospitalisation

Overall study start date

01/05/2005

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

Age group

Senior

Sex

Both

Target number of participants

60

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)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.uzbrussel.be/>

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

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	01/03/2012		Yes	No